NOVEN PHARMACEUTICALS INC
Form 10-K
March 16, 2005

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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, 2004 **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 þ No o

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

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

As of March 1, 2005, there were 23,505,846 shares of Common Stock outstanding.

The aggregate market value of such voting stock held by non-affiliates of the registrant was approximately $514 million (computed by reference to the price at which the voting stock was last sold on June 30, 2004, the last business day of the registrant s most recently completed second fiscal quarter).

DOCUMENTS INCORPORATED BY REFERENCE:

Part III: Portions of registrant s Proxy Statement for its 2005 Annual Meeting of Shareholders.

NOVEN PHARMACEUTICALS, INC.

Annual Report on Form 10-K
for the year ended December 31, 2004

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FORWARD-LOOKING INFORMATION

Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. These statements are made to enable a better understanding of our business, but because these forward-looking statements are subject to many risks, uncertainties, future developments and changes over time, actual results may differ materially from those expressed or implied by such forward-looking statements. Examples of forward-looking statements are statements about anticipated financial or operating results, financial projections, business prospects, future product performance, future research and development results, anticipated regulatory filings and approvals, and other matters that are not historical facts. Such statements often include words such as anticipates, believes, estimates, expects, intends, may, plans, could, should, seeks, will, would or similar expressions.

These forward-looking statements are based on the information that was currently available to us, and the expectations and assumptions that were deemed reasonable by us, at the time the statements were made. We do not undertake any obligation to update any forward-looking statements in this report or in any of our other communications, except as required by law, and all such forward-looking statements should be read as of the time the statements were made, and with the recognition that these forward-looking statements may not be complete or accurate at a later date.

Many factors may cause or contribute to actual results or events being materially different from those expressed or implied by forward-looking statements. Although it is not possible to predict or identify all such factors, they include those set forth under Factors Affecting Our Business and Prospects beginning on page 52 of this report.

PART I

Item 1. Business.

General

We develop and manufacture advanced transdermal patches utilizing our proprietary drug delivery technologies. Our principal commercialized products are prescription transdermal patches for use in menopausal hormone therapy (HT). These products consist of:

Vivelle-Dot (estradiol transdermal system), the most dispensed transdermal estrogen therapy product in the United States and the smallest estrogen patch approved by the United States Food and Drug Administration (FDA). This product is marketed under the brand name Estradot outside the United States and Japan.

Vivelle® (estradiol transdermal system), an estrogen patch utilizing an older generation of our transdermal delivery technology. This product is marketed under the brand name Femiest® in Japan and Menorest in most countries outside the United States and Canada.

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CombiPatch® (estradiol/norethindrone acetate transdermal system), was the first combination estrogen/progestin transdermal patch approved by the FDA for the treatment of menopausal symptoms. This product is marketed under the brand name Estalis® outside the United States.

Our business strategy is focused on diversifying our product offerings beyond HT through strategic collaborations and new product development. The new product applications that we are exploring consist of both new and proprietary formulations as well as generic versions of existing products where we believe our proprietary technology may be beneficially applied.

We submitted an Abbreviated New Drug Application (ANDA) to the FDA in July 2003 seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch for the management of chronic pain that contains fentanyl, an opioid analgesic and a Schedule II controlled substance. Our ANDA for this product was accepted for filing in October 2003 and is under review at the FDA. The patent and exclusivity period for Duragesic® expired in January 2005 and the market for this product presently consists of the branded product, an authorized generic and a generic version of Duragesic®. We have licensed our fentanyl patch to Endo Pharmaceuticals Inc. (Endo). Endo and Noven are working together to develop additional prescription patches.

We have a New Drug Application (NDA) pending with the FDA for a once-daily methylphenidate patch for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). We believe that this product, if approved by the FDA, may address several issues associated with existing therapies and compete in the United States market for ADHD therapies. We have licensed the exclusive global rights to market our methylphenidate patch to Shire Pharmaceuticals Group plc (Shire). Noven and Shire are working to address issues raised in a not approvable letter received from the FDA in April 2003 relating to the NDA for our methylphenidate patch.

We are working with Procter & Gamble Pharmaceuticals, Inc. (P&G Pharmaceuticals) to develop prescription transdermal delivery systems for Hypoactive Sexual Desire Disorder (HSDD). The products under development explore follow-on product opportunities for Intrinsa®, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women diagnosed with HSDD. P&G Pharmaceuticals withdrew its NDA for Intrinsa® in December 2004 based on feedback from an FDA Advisory Committee and has stated its intention to file a new NDA with additional clinical data.

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

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

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Novogyne Pharmaceuticals

Our menopausal hormone therapy products are marketed and sold through Novogyne Pharmaceuticals (Novogyne), a joint venture that we formed with Novartis Pharmaceuticals Corporation (Novartis) in 1998 to market and sell women s prescription healthcare products. We own a 49% equity interest in the joint venture company and Novartis owns the remaining 51% equity interest. The joint venture company is a Delaware limited liability company organized under the name Vivelle Ventures LLC and doing business under the Novogyne name. In 2004, our equity in earnings of Novogyne, a non-cash item, represented substantially all of our income before income taxes.

Novogyne presently markets our Vivelle-Dot, Vivelle®, and CombiPatch® products in the United States. Novogyne s sales and marketing efforts have caused the Vivelle® product line to become the most dispensed product family in the transdermal estrogen therapy (ET) category, with a greater than 40% share of monthly total prescriptions dispensed in the United States as of December 2004.

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

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

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

The joint venture operating agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If Noven is the

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purchaser, then Noven must pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. Novartis is a larger company with greater financial resources, and therefore may be in a better position to be the purchaser if the provision is triggered. In addition, this buy/sell provision may have an anti-takeover effect on Noven since a potential acquirer of Noven will face the possibility that Novartis could trigger this provision at any time and thereby require any acquirer to either purchase Novartis interest in Novogyne or to sell its interest in Novogyne to Novartis.

Growth Strategy

Our strategy for growth and continued profitability is to broaden the commercialized applications for our proprietary transdermal drug delivery technology to further our leadership position in the transdermal drug delivery field. This strategy includes:

- identifying and initiating development of new product opportunities that utilize our existing delivery technology;
- licensing these products at various stages of development to industry partners for completion of development and commercialization;
- developing and/or acquiring new technologies that will permit us to continue the cycle of development and partnering;
- remaining attentive to opportunities where it would be advantageous to market our own products through a specialty sales organization; and
- seeking to enhance the opportunity presented by our collaboration with Novartis through Novogyne by licensing certain of our developmental women s health products to Novogyne and by expanding Novogyne s product range beyond transdermal HT products.

In pursuing our strategy, we intend to focus on developing products in a range of therapeutic areas, including hormone therapy and central nervous system conditions, such as ADHD, HSDD and pain management.

Target areas for new product development may include proprietary prescription products, generic prescription products, or select over-the-counter product opportunities that offer desirable financial return. We generally seek to develop and commercialize these products through agreements with strategic industry partners. We believe that the introduction of our products in diverse therapeutic categories with multiple partners will work to reduce our reliance on any particular product or partner.

We regularly review our corporate strategies to evaluate the suitability and effectiveness of such strategies in light of evolving business, industry, market and other conditions. No assurance can be given that we will implement all or part of our long-term strategy, that our strategies may not change from time to time or that any strategy we adopt will be successful.

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Transdermal Drug Delivery

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

Our most advanced patches utilize our patented DOT Matrix® patch technology. DOT Matrix® is a highly efficient class of diffusion-based drug-in-adhesive patch technology that can often deliver more drug through a smaller patch area than competitive patches, without using irritating skin permeation enhancers and without compromising adhesion. We believe that reduced patch size can have a beneficial effect on patient preference and provide a competitive advantage over patches that deliver similar compounds through a larger patch. DOT Matrix® technology may also permit us to develop patient-friendly patches in cases where, due to the nature of the compound, competitors products could not deliver a therapeutic dose without making the patch objectionably large.

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

We believe that our technology enables us to develop patient-friendly transdermal systems that can reduce skin irritation sometimes associated with patches, improve adhesion, minimize patch size and improve patch appearance. Our patches are capable of being modified to deliver a wide variety of chemical entities.

Hormone Therapy Products

Overview

Our menopausal HT products consist of:

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

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

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

We currently derive a significant portion of our revenues from our HT products. Our total HT-related revenues were $39.8 million, $41.2 million and $54.5 million for 2004, 2003 and 2002, respectively, which represented 87%, 96% and 98% of our revenues in these years, respectively.

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

HT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with use of oral combination HT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin after an average follow-up period of 5.2 years because the oral combination HT product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, the National Cancer Institute (NCI) published the results of an observational study in which it found that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. Since 2002, several other published studies have identified increased risks from the use of HT. As a result of the findings from the WHI and other studies, the FDA has required that black box labeling be included on all HT products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention. Since the July 2002 publication of the WHI and NCI study data, total United States prescriptions have declined for substantially all HT products, including our products in the aggregate. For a discussion of the effects of these studies on our prescription rates and certain risks that we may face as a result of these studies, see Management s Discussion and Analysis of Financial Condition and Results of Operations Overview.

Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage. In particular, a private foundation has announced a new five-year study aimed at determining whether ET use by women aged 40 to 55 reduces the risk of heart disease. This study also seeks to determine if transdermal estrogen patches (as well as alternative dosage forms such as a gel and a cream) are more or less beneficial than a conjugated oral product. The foundation s website indicates that Vivelle-Dotwill be used as the estrogen patch in the study. Noven is not a sponsor of this study and has not reviewed the protocol. Among other risks related to this study, the market for Vivelle-Dot would likely be adversely affected if this study finds our transdermal estrogen patch is less beneficial than other dosage forms, and we could be subject to product liability claims if our products are found to increase the risk of adverse health consequences. To date we have been named as a defendant in one

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product liability lawsuit involving our HT products and we may have liability with respect to other actions in which we have not, to date, been made a party. See Item 3 Legal Proceedings.

First Generation Transdermal Estrogen Patch

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

This product has been approved for marketing by the FDA, as well as by regulatory authorities in many foreign countries, for the treatment of menopausal symptoms and the prevention of osteoporosis. Marketing rights to this product are held by Novogyne in the United States, by Aventis Pharma AG (Aventis) in Japan, and by Novartis Pharma AG (Novartis Pharma) in all other territories. Novartis Pharma, an affiliate of Novartis, is selling this product under the brand name Menorest in a number of foreign countries. Novogyne and Novartis Pharma s Canadian affiliate market this product under the brand name Vivelle® in the United States and Canada, respectively, and Aventis markets this product under the brand name Femiest® in Japan. This product is in the process of being phased out in several jurisdictions (including certain dosage strengths in the U.S.) where Vivelle-Dot, our second generation ET patch, has gained acceptance.

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

Second Generation Transdermal Estrogen Patch

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

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Novogyne markets Vivelle-Dot in the United States and Aventis has marketing rights for Vivelle-Dot in Japan. Novartis Pharma holds the rights to market Vivelle-Dot under the name Estradot in all countries other than the United States, Canada and Japan. The agreement also grants Novartis Pharma marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by us.

Under the terms of the agreement, Novartis Pharma is responsible for seeking approval to market Estradot in its territories. The product has been approved for marketing in over 30 foreign countries and the regulatory authorities of other countries are reviewing Novartis Pharma s registration applications. Novartis Pharma has launched the product in Germany, in Spain (without the benefit of government reimbursement) and in a number of smaller European countries. We have been advised that Novartis Pharma is in the process of launching the product through a marketing partner in the United Kingdom and France and is in negotiations with regulatory authorities in Italy with respect to the reimbursement for Estradot in Italy. We cannot assure that Novartis Pharma will be successful in launching Estradot in these or other countries. The profitability of Estradot and our other products sold in the European Union may also be negatively affected by parallel trade practices whereby a licensed importer may take advantage of price disparity between markets by purchasing our products in a market with a relatively lower price and then importing them into a country with a relatively higher price. Novartis Pharma markets several other estrogen patches in addition to our products and Novartis Pharma may derive higher gross margins on the sale of its other products compared to ours. If pricing, government reimbursement and labeling issues are resolved, we expect that the growth of Estradot sales will depend, in part, on Novartis Pharma s willingness and ability to convert sales of its existing patches to Estradot. We cannot assure that Novartis Pharma will choose to actively convert sales of its existing patches to Estradot.

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

Transdermal Combination Estrogen/Progestin Patch

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

Novogyne acquired marketing rights to the product in March 2001 from Aventis (which was then our exclusive worldwide licensee for the product) and markets the product under the brand name CombiPatch® in two dosage strengths in the United States. Novartis Pharma holds the right to market this product outside of the United States and Japan and is marketing this product under the brand name Estalis® in a number of foreign countries. In 2001, we entered into a development

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agreement with Novartis Pharma relating to future generations of combination estrogen/progestin patch products.

Estalis® is presently approved in one dosage strength in most European countries. Novartis Pharma has advised us that they plan to seek marketing approval and commercialization of a lower dosage strength when and if a next generation combination product is developed. No assurance can be given that we will complete development of a next generation combination estrogen/progestin patch or that approval will be obtained, and the timing of any launch of a next generation combination estrogen/progestin patch product cannot be predicted. We expect that growth in this market will be limited unless and until a next generation combination estrogen/progestin patch product is developed, approved and launched.

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

Transmucosal Product

Our first transmucosal delivery system, DentiPatch®, utilizes 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 1996 and was the first FDA-approved oral transmucosal patch. We launched the product in the United States in 1997. The product is indicated for the reduction of pain from oral injections and for the production of mild topical anesthesia prior to superficial dental procedures. It is the first topical anesthetic clinically proven to reduce pain when large needles are inserted to the bone. DentiPatch® is currently marketed in the United States through a network of independent distributors. Sales of DentiPatch® are not material to our results of operations.

Development Collaborations

Endo

In July 2003, we submitted an ANDA to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch containing fentanyl, an opioid analgesic and a Schedule II controlled substance, and is indicated for the management of chronic pain in patients who require continuous opioid analgesia and whose pain cannot be controlled by lesser means. Our ANDA for this product was accepted for filing as of October 1, 2003 and is under review at FDA. Johnson & Johnson s patent and exclusivity status for Duragesic® expired in January 2005, after which the FDA approved the fentanyl transdermal system ANDA filed by Mylan Laboratories. Also in January 2005, the FDA denied several citizen petitions intended to prevent or delay the approval of certain generic versions of Duragesic®.

In February 2005, the FDA approved a Supplemental New Drug Application filed by Johnson & Johnson for new labeling for its Duragesic® product. We have been advised by the FDA that all pending ANDAs relating to the Duragesic® product, including our ANDA, will be required to be amended prior to approval to reflect recent changes in the Duragesic® label. We are currently working with the FDA with respect to a revised label for our fentanyl patch. Once finalized, we will repackage existing inventory to reflect the revised labeling. We understand that there are other pending Duragesic® ANDAs, and we are unable to predict the timing or the impact of the required

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labeling changes on any pending ANDA, nor are we able to predict the timing of approval of any pending ANDA.

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

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

As of December 31, 2004, we have incurred $10.8 million for the cost of pre-launch inventories for our fentanyl patch. If approval is not ultimately received or is delayed, our agreement with Endo provides that the parties will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed upon formula and we may be unable to recover our share of such costs, which could be up to approximately $6.0 million.

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

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

Shire

We have developed a once-daily transdermal methylphenidate patch for the treatment of ADHD. ADHD is the most commonly diagnosed and the most widely studied behavioral disorder in children in the United States. ADHD is characterized by developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity symptoms. The disorder typically causes functional impairment that can limit success and create hardship in school, and in social and familial relationships. As children age, the symptoms can lead to serious conduct disorders, criminal

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behavior, substance abuse and accidental injuries. Methylphenidate is a stimulant and designated as a Schedule II controlled substance by the United States Drug Enforcement Administration (DEA).

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

In June 2002, we filed with the FDA an NDA for a methylphenidate transdermal system. In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market our methylphenidate patch to Shire for payments of up to $150.0 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25.0 million was paid upon closing of the transaction in April 2003; (ii) $50.0 million is payable upon receipt of final marketing approval for our methylphenidate patch by the FDA; and (iii) three installments of $25.0 million each are payable upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual net sales of our methylphenidate patch, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, we entered into a long-term supply agreement under which we expect to manufacture and supply our methylphenidate patch to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, our revenues and profits from sales of our methylphenidate patch would be adversely affected.

In April 2003, Noven received a not approvable letter from the FDA relating to our methylphenidate patch NDA. In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire are proceeding with the development of the methylphenidate patch. Development efforts include additional clinical studies, including another Phase 3 study. Pursuant to the agreements between the parties, Shire is managing these studies and Noven has committed to fund them. Noven s direct costs incurred in pursuit of approval are expected to be deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven s research and development expenses in 2004 and are not expected to impact research and development expenses in 2005, although the direct expenses incurred in pursuit of FDA approval will reduce Noven s cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of December 31, 2004, the amount of deferred revenues was $5.7 million (which excludes the $5.0 million of deferred revenues related to the repurchase right described below) and Noven does not expect the prospective cost in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for our methylphenidate patch.

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Under Noven s agreements with Shire, Shire has certain rights to terminate the license to our methylphenidate patch, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable product. If Shire were to terminate on this basis, all product rights would revert to Noven, and Noven would retain the $25.0 million previously paid by Shire. Shire also has the right to require Noven to repurchase the product rights to our methylphenidate patch for $5.0 million under certain circumstances.

In June 2004, we entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD. The agreement provides for the payment to Noven of up to $5.0 million if certain development milestones are achieved. The product is in pre-clinical development.

P&G Pharmaceuticals

In April 2003, we established a collaboration with P&G Pharmaceuticals for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa®, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women diagnosed with HSDD. P&G Pharmaceuticals withdrew its NDA for Intrinsa® in December 2004 based on feedback from an FDA Advisory Committee and has stated its intention to file a new NDA with additional clinical data.

Research and Development

Our research and development strategy is to identify drugs that can be delivered transdermally and which we believe have substantial market potential, as well as those that we believe can be improved by using our patented technologies. We typically seek to develop products that use approved drugs that currently are being delivered to patients through means other than transdermal delivery, but we may also explore new formulations or proprietary products where we believe our technology may be beneficially applied. As part of our strategy, we seek to supplement our research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies.

In addition to the pre-clinical studies being conducted in connection with our Endo and Shire collaborations, we have entered into a number of other early stage development agreements with other pharmaceutical companies to determine the feasibility of transdermal delivery of various compounds, including our partners proprietary compounds.

For the years ended December 31, 2004, 2003 and 2002, we spent $9.9 million, $8.1 million and $11.6 million, respectively, for research and development activities, which does not include amounts we expended on additional clinical studies for our methylphenidate patch since those amounts were offset against the deferred revenue we received from Shire under our agreement with Shire. Our research and development expense may vary significantly from quarter to quarter depending on product development cycles, the timing of clinical studies and whether we or a third party are funding development. We intend to focus on long-term growth prospects, and, therefore, may incur higher than expected research and development expenses in a given period rather than delay clinical activities. These variations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations.

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

Competition

The markets for our products are highly competitive. All drug delivery products that we are developing may face competition from conventional forms of drug delivery (i.e., oral and parenteral), from alternate forms of drug delivery, such as controlled release oral delivery, liposomes, implants, gels and creams and possibly from alternate non-drug therapies. Some or all of the products being marketed or developed by us face, or will face, competition from other transdermal products that deliver the same drugs to treat the same indications. In addition, medical science is constantly evolving. As developments in medicine are made, products may become obsolete or fall out of favor with physicians.

Competition in drug delivery systems is generally based on a company s marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. As a general matter, transdermal drug delivery systems are more expensive to manufacture than oral formulations. Acceptance by physicians and other health care providers, including managed care groups, is also critical to the success of a product. The first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share for a period of time. In a highly competitive marketplace and with evolving technology and medical science, there can be no assurance that additional product introductions or medical developments by others will not render our products or technologies noncompetitive or obsolete. We also compete with other drug delivery companies in the establishment of business arrangements with large pharmaceutical companies to assist in the development or marketing of products. It is also possible that Vivelle-Dot or other Noven products could, prior to the expiration of the applicable patent periods, face competition from a generic product if approved through the ANDA process or from a functionally-equivalent product that avoids our patents.

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

The market for ADHD drugs is also highly competitive, with a product mix that includes generic methylphenidate, long-acting formulations, other stimulant medications, medications not containing Schedule II controlled substances, and a variety of other drug types. Other products which may have improved safety and efficacy profiles are also in development. Shire currently

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markets non-methylphenidate products for the treatment of ADHD, and we cannot assure that Shire will market our methylphenidate patch aggressively or effectively if it is approved, or that our methylphenidate patch will compete effectively against extended release oral formulations of methylphenidate and/or other ADHD medications, especially those not involving controlled substances. Some of the companies marketing competitive ADHD products are substantially larger and have greater financial resources than Shire does, including Johnson & Johnson, Novartis and Eli Lilly. Strattera®, a non-stimulant, non-controlled substance therapy marketed by Eli Lilly, has gained significant market share since its launch in 2003. If Strattera® or other therapies in development become recognized as therapeutically superior to stimulants, or are preferred by physicians, parents and/or patients, the market for stimulants, including our developmental methylphenidate patch product, would be adversely affected.

If approved by the FDA, our fentanyl transdermal system will face a highly competitive market. Currently, the market consists of: (i) Duragesic®, the branded product, (ii) a product supplied by the branded manufacturer and sold as a generic by a third party, and (iii) a generic version of Duragesic®. In addition to our ANDA, we understand that several additional companies have submitted ANDA s for a transdermal fentanyl system. In the market for generics, the first products to be commercialized typically achieve significant market share. As competing generic manufacturers receive regulatory approvals, market share, revenues and gross profit of those companies already on the market typically decline, in some cases dramatically. Companies seeking to enter the market with newly approved products will generally seek to gain market share through price reductions and other customer incentives, which can have the effect of reducing pricing and market share for all competitors in the market. Accordingly, we expect the level of market share, revenues and gross profit derived from our fentanyl patch will depend upon the timing of any FDA approval for our product, the number of competitors then in the market, and the timing of our launch in relation to competing approvals and launches.

Dependence on Licensees and Joint Venture

During 2004, 52% and 31% of our revenues were generated from sales to, and contract revenues, fees and royalties received from, Novogyne and Novartis Pharma and its affiliates, respectively, and substantially all of our income before income taxes was attributable to our equity in Novogyne s earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novartis Pharma, Novogyne and possibly Endo, Shire, P&G Pharmaceuticals and other collaboration partners, as well as fees, milestone payments, profit sharing and royalties generated from their sales of our transdermal delivery systems, for a significant portion of our expected revenues. No assurance can be given regarding the amount and timing of such revenues. Failure of these parties to successfully market our products would cause the quantity of products purchased from us and the amount of fees, milestone payments and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and results of operations. We expect to be able to influence the marketing of Vivelle®, Vivelle-Dot and CombiPatch® in the United States through our participation in the management of Novogyne, but the Management Committee of Novogyne is comprised of a majority of Novartis representatives, and we will not be able to control those matters. Our agreements with our marketing partners impose certain obligations on them, but there can be no assurance that such agreements will provide us with any meaningful level of protection or cause these companies to perform at a level that we deem satisfactory. Further, these companies and their affiliates sell competing products, both in the United States and abroad, and it is possible that they will promote their other competitive products at our expense. Any reduction in the level of support and promotion that these companies provide to our products, whether as a result of

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their focus on other products or otherwise, could have a material adverse effect on our business, results of operations, financial condition and prospects. Because of the legal complexities inherent in attempting to establish damages in litigation arising under agreements such as our agreements with Novartis, Shire and Endo, those agreements may not, as a practical matter, provide us with an adequate remedy for our partner s breach.

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

Manufacturing

We conduct our manufacturing operations in a single facility comprised of two approximately 40,000 square foot buildings located on approximately 10 acres in Miami-Dade County, Florida. This facility has been inspected by the FDA and by the Medicines and Healthcare Products Regulatory Agency of the United Kingdom and found to be in compliance with applicable regulatory requirements. This facility has also been certified by the DEA to manufacture products containing controlled substances. To bring new products to market as quickly as possible, we will seek to have the manufacturing capacity to produce the new product prior to obtaining FDA approval and, in certain circumstances, to begin manufacturing the new product prior to obtaining FDA approval. We are currently expanding our manufacturing area to facilitate the manufacture and storage of our methylphenidate patch and our transdermal fentanyl patch. In addition, we have supplemented our manufacturing facilities on our existing site with leased space located in close proximity to our existing site for the storage, and, if necessary, manufacture of new products. If FDA approval for our methylphenidate patch, our fentanyl transdermal patch or other products under development is not obtained, we may not be able to recover our upfront costs to expand our manufacturing facilities as well as raw material and other costs associated with manufacturing pre-launch supplies.

Some raw materials essential to our business are readily available from multiple sources. Certain raw materials and components used in the manufacture of our products (including essential polymer adhesives and other critical components) are, however, available from limited sources, and in some cases, a single source. The NDA for our methylphenidate patch includes only one supplier of the active pharmaceutical compound. This same supplier is also the only source of the active pharmaceutical compound for which we have sought approval under the ANDA for our transdermal fentanyl system. In addition, the DEA controls access to controlled substances (including methylphenidate, amphetamine and fentanyl), and we must receive authorization from the DEA to obtain these substances. Any curtailment in the availability of such raw materials could result in production or other delays, and, in the case of products for which only one raw material supplier exists, could result in a material loss of sales, with consequent adverse effects on our business and results of operations. In addition, because most raw material sources for transdermal patches must generally be approved by regulatory authorities, changes in raw material suppliers may result in

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production delays, higher raw material costs and loss of sales, customers and market share. Some raw materials used in our products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, there can be no assurance that such companies will not expand their restrictions to include our applications.

For information with respect to recent production issues, see Management s Discussion and Analysis Certain Items that Affect Historic or Future Comparability.

Marketing & Sales

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

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

Under the Novogyne joint venture agreements, Novartis has responsibility for Novogyne s distribution function (including managing the relationship and agreements with wholesale drug distributors and managed care organizations), while Noven has responsibility for the day-to-day management of Novogyne s marketing efforts and sales force. In fulfilling the marketing and sales function, we believe that we have established significant expertise in this area. We believe this expertise has helped lead the Vivelle® product line to become the most dispensed product family in the U.S. transdermal ET category. We also seek to use this expertise more broadly to help us identify and evaluate the commercial potential of new product development projects that may help advance our growth strategy.

Patents and Proprietary Rights

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained 31 United States patents and approximately 200 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have approximately 140 pending patent applications worldwide.

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

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

Although there is a statutory presumption as to a patent s validity, the issuance of a patent is not conclusive as to such validity, or as to the enforceable scope of the claims of the patent. We cannot assure that our patents or any future patents will prevent other companies from developing similar or functionally equivalent products. We cannot assure that we would have the resources to prosecute an action to enforce our patent rights against an alleged infringer or that we would be successful in any infringement action that we elect to bring. Likewise, we cannot assure that we would have the resources to defend an infringement action or that we would be successful in any such defense. Furthermore, we cannot assure that any of our future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that our processes or products will not infringe upon the patents of third parties. In addition, since our patents typically cover our product formulation rather than the compound being delivered, competitors may seek to create functionally equivalent products (i.e., patches delivering the same compound over the same time period to treat the same indication) that avoid our patents. In those cases, we may face competition from functionally equivalent products even before our patents expire.

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

Trademarks

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

DOT Matrix® and DentiPatch® are registered trademarks of Noven Pharmaceuticals, Inc.;

Vivelle® is a registered trademark of Novartis Corporation;

Estradot (foreign) is a registered trademark of Novartis AG;

CombiPatch® and Estalis® (U.S.) are registered trademarks of Vivelle Ventures LLC;

Vivelle-Dot and Menorest are trademarks of Novartis AG;

Femiest® is a registered trademark of Aventis Pharma S.A. in Japan;

Duragesic® is a registered trademark of Johnson & Johnson;

Concerta® is a registered trademark of Alza Corporation;

Strattera® is a registered trademark of Eli Lilly and Company;

Intrinsa is a trademark of Procter & Gamble Pharmaceuticals, Inc.;

Vioxx® is a registered trademark of Merck & Co., Inc.;

Zoloft® is a registered trademark of Pfizer, Inc.; and

Adderall XR® is a registered trademark of Shire.

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Government Regulation

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

The marketing of pharmaceutical products requires the approval of the FDA in the United States. The FDA has established regulations, guidelines and safety standards, which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of pharmaceutical products. The process of obtaining FDA approval for a new product may take several years or more and is likely to involve the expenditure of substantial resources. The steps required before a product can be produced and marketed for human use typically include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Exemption (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials; (iv) submission to the FDA of a New Drug Application (NDA); and (v) review and approval of the NDA by the FDA. Approval of a product by the FDA does not serve as a guaranty of the product s safety or efficacy. In light of widely publicized events surrounding HT products and such other products as Vioxx® and Zoloft®, both citizen s groups and interests in the United States Congress have called for investigation and possible reform of the FDA s product approval and safety monitoring process to help better ensure the safety and efficacy of products approved by the FDA.

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

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

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The Hatch-Waxman Act further provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, the FDA cannot grant final approval to any other Paragraph IV filer. If an ANDA containing a Paragraph IV certification is successful, it generally results in higher initial market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for generic drug products, we may lose significant advantages to a competitor who was first to file an ANDA containing a Paragraph IV certification. Disputes have arisen as to which of several ANDA applicants is first to file, and thus potentially entitled to exclusivity. FDA administration of its first to file policies has been the subject of unresolved litigation, and administrative and legislative activity. Thus, Noven cannot assure that even if it is otherwise entitled to such exclusivity, it will ultimately be awarded.

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

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

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or ANDA in a timely manner. The FDA may deny an NDA or ANDA if applicable regulatory criteria are not satisfied or it may require additional clinical testing. Even if such data is submitted, the FDA may ultimately deny approval of the product. Further, if there are modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in manufacturing facility, an NDA or ANDA notification may be required to be submitted to the FDA and FDA approval required prior to implementation of the change. 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 that have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

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

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to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

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

Failure to comply with governmental regulations may result in fines, warning letters, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales, withdrawal of previously approved marketing applications and criminal prosecution.

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

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

Employees

As of December 31, 2004, we had approximately 340 employees; approximately 223 of which are engaged in manufacturing, process development, quality assurance and quality control, 22 in research and development, 12 in clinical research and regulatory affairs, and 83 in marketing and administration. No employee is represented by a union and we have never experienced a labor-related work stoppage. We believe our employee relations are good. In addition to the employees employed directly by us, Novogyne has a contract sales force of approximately 120 individuals that we manage under the terms of the Novogyne joint venture agreements.

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Seasonality

Although our business is affected by the purchasing patterns of wholesale drug distributors, there are no significant seasonal aspects to our existing HT business. We may face increased seasonality if our ADHD product is approved by the FDA and successfully commercialized since ADHD products are generally prescribed and dispensed more frequently during the school year than in the summer months.

Available Information

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

Item 2. Properties.

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

We lease approximately 15,700 square feet of office space in a neighboring facility for certain administrative functions and an additional 78,600 square feet of industrial space for warehousing which, depending on need, may also be used for manufacturing new products. In addition, we own five acres of vacant land on a contiguous site that we believe could accommodate new buildings for a variety of manufacturing, warehousing and developmental purposes. We believe that our facilities are in satisfactory condition, and are suitable for their intended use and have adequate capacity for the manufacture of our HT products. We are currently expanding our manufacturing area to facilitate the manufacture and storage of our methylphenidate patch and our transdermal fentanyl patch. In addition, as noted above, we have supplemented our manufacturing facilities on our existing site with leased space located in close proximity to our existing site for the storage, and, if necessary, manufacture of new products.

Our sole manufacturing facility, our research and development activities, as well as our corporate headquarters and other critical business functions, are located in an area subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business,

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earnings and competitive position could be materially adversely affected in the event of a major windstorm or other casualty.

Item 3. Legal Proceedings.

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

Plaintiff filed the above referenced action on behalf of a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. The complaint alleges that, during the subject period, Noven and its officers named as defendants violated the Securities Exchange Act of 1934 by making false and misleading statements in its public disclosures regarding our methylphenidate patch. Following the filing of Plaintiff s complaint, five other substantially similar complaints were filed against Noven and its officers named as defendants in the above referenced action. In December 2004, the court entered an order appointing Equitec-Cole Investor Group as the lead plaintiff and, on or about February 11, 2005, the Plaintiffs filed an Agreed Motion and Proposed Order of Voluntary Dismissal seeking that the complaint be dismissed without prejudice. Noven believes the lawsuit is without merit. If the lawsuit is not ultimately dismissed or if the Plaintiffs decide to refile this lawsuit, Noven intends to vigorously defend the lawsuit. The lawsuit, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability, if any, with respect to the lawsuit is presently not determinable.

HT Litigation

In July 2004, an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including our CombiPatch® product, which is manufactured by Noven and sold by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount. In January 2005, the plaintiffs agreed to substitute Aventis for Noven and Novartis in this case. The parties are in the process of drafting the necessary documents to effect the substitution of Aventis and dismissal without prejudice of Noven and Novartis.

Novartis has advised Noven that Novartis has been named as a defendant in at least 11 additional lawsuits that include approximately 22 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches (Vivelle®, Vivelle-Dot and CombiPatch®) sold by Novogyne. To date neither Noven nor Novogyne has, to Noven s knowledge, been named as a party to these additional lawsuits. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. The outcome of these product liability lawsuits cannot ultimately be predicted.

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

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

We did not submit any matters to a vote of stockholders during the quarter ended December 31, 2004.

Executive Officers of the Registrant

Set forth below is a list of the names, ages, positions held and business experience of the persons serving as our executive officers as of March 1, 2005. Officers serve at the discretion of the Board of Directors. There is no family relationship between any of the executive officers or between any of the executive officers and any of our directors, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Eduardo G. Abrao, M.D. Dr. Abrao, age 62, has been Vice President Clinical Development & Chief Medical Officer of Noven since September 2003. Prior to joining Noven, Dr. Abrao served as the Vice President, Regulatory Affairs and Drug Safety of Berlex Laboratories, Inc. from March 2002 to October 2002. From 1996 to 2002, Dr. Abrao served Otsuka America Pharmaceutical, Inc. in a variety of regulatory and operational positions, most recently as its President and Chief Operating Officer. From 1989 to 1996, Dr. Abrao was Vice President, International Medical Department with Marion Merrell Dow/Hoechst Marion Roussel.

Diane M. Barrett. Ms. Barrett, age 44, has been with Noven since August 2000 and, since May 2003, has served as Vice President & Chief Financial Officer. From 1997 to 2000, Ms. Barrett served as Vice President and Chief Financial Officer of BioNumerik Pharmaceuticals, Inc. and, from 1990 to 1997, served Cordis Corporation in a variety of finance positions, most recently as Treasurer. Prior to joining Cordis, Ms. Barrett was a manager with Arthur Andersen & Co.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 39, has been with Noven since November 1998 and, since November 2000, has served as Vice President Strategic Alliances, General Counsel & Corporate Secretary. From 1995 through 1998, Mr. Eisenberg served as Associate General Counsel and then as Acting General Counsel of IVAX Corporation. Prior to joining IVAX, he was a lawyer in the corporate securities department of the law firm of Steel Hector & Davis.

W. Neil Jones. Mr. Jones, age 52, 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 46, has been with Noven since March 1990 and, since June 2000, has served as Vice President & Chief Technical Officer. From December 1986 to March 1990, he served Paco Research Corp. as Manager Product Development. From April 1983 to December 1986, he served Key Pharmaceuticals, Inc. as Senior Research Engineer.

Robert C. Strauss. Mr. Strauss, age 63, 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 as a Director of IVAX Corporation. From 1983 to 1997,

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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) and Columbia Laboratories, Inc. (pharmaceuticals).

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PART II

Item 5. Market for Registrant s Common Equity Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our Common Stock is listed on the Nasdaq Stock Market and is traded under the symbol NOVN. As of March 1, 2005, we had 288 stockholders of record of our Common Stock. We have never paid a cash dividend on our Common Stock and do not anticipate paying cash dividends in the foreseeable future. The following table sets forth, for the periods indicated, the high and low sale prices for the Common Stock as reported on the Nasdaq Stock Market.

	High Price	Low Price
First Quarter, 2004	$ 25.96	$ 15.05
Second Quarter, 2004	23.65	16.75
Third Quarter, 2004	22.23	17.76
Fourth Quarter, 2004	24.50	14.62
First Quarter, 2003	$ 14.69	$ 7.30
Second Quarter, 2003	14.98	8.10
Third Quarter, 2003	12.64	9.96
Fourth Quarter, 2003	15.80	9.69

The following table provides information with respect to our stock repurchases during the fourth quarter of 2004:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program[1]
October 1, 2004 to October 31, 2004				$ 23,711,040
November 1, 2004 to November 30, 2004				$ 23,711,040
December 1, 2004 to December 31, 2004				$ 23,711,040
Totals				$ 23,711,040

(1) In March 2003, we announced a stock repurchase program authorizing the buy back of up to $25.0 million of our Common Stock. There is no expiration date specified for this program.

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Item 6. Selected Financial Data.

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

	Years Ended December 31,				
Statement of Operations Data:	2004	2003	2002	2001	2000
Net revenues	$ 45,891	$ 43,166	$ 55,372	$ 45,947	$ 42,924
Expenses:					
Cost of products sold	20,101	19,482	22,973	20,376	19,219
Research and development	9,911	8,082	11,634	10,973	13,621
Marketing, general and administrative	17,271	15,858	14,257	11,554	8,737
Total expenses	47,283	43,422	48,864	42,903	41,577
(Loss) income from operations	(1,392)	(256)	6,508	3,044	1,347
Equity in earnings of Novogyne	17,641	17,094	14,368	14,013	9,294
Interest income, net	999	659	822	1,770	1,385
Income before income taxes	17,248	17,497	21,698	18,827	12,026
Income tax expense (benefit)	6,024	6,301	7,819	6,736	(7,608)
Net income	$ 11,224	$ 11,196	$ 13,879	$ 12,091	$ 19,634
Basic earnings per share	$ 0.48	$ 0.50	$ 0.62	$ 0.54	$ 0.90
Diluted earnings per share	$ 0.46	$ 0.49	$ 0.60	$ 0.51	$ 0.84
Balance Sheet Data:					
Cash and cash equivalents	$ 93,958	$ 83,381	$ 58,684	$ 49,389	$ 40,976
Total assets	201,975	170,984	138,502	137,028	104,031
Capital lease obligation	235		5	13	265
Deferred license revenue	39,085	50,005	29,445	32,758	27,109
Stockholders equity	129,039	108,823	96,741	81,898	65,277

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

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

An overview of Noven and our Novogyne joint venture;

A review of certain items that affect the historical or future comparability of our results of operations;

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

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

An outlook that includes our current financial guidance for 2005; and

A review of cautionary factors that could have a material adverse effect on our business, financial condition and results of operations.

This discussion should be read in conjunction with Noven and Novogyne s 2004 financial statements and the related notes included in this Form 10-K.

Overview

We develop and manufacture advanced transdermal patches and presently derive substantially all of our revenues from sales of transdermal patches for use in menopausal hormone therapy. In the United States, our HT products are marketed and sold by Novogyne Pharmaceuticals, the joint venture that we formed with Novartis in 1998. Our business, financial position and results of operations currently depend on Novogyne and its marketing of our three principal HT products Vivelle®, Vivelle-Dot and CombiPatch® in the United States. A discussion of Novogyne s results and their impact on our results can be found under the caption Results of Operations Equity in Earnings of Novogyne.

In all countries other than the United States, Canada and Japan, we have licensed the marketing rights to these products to Novartis Pharma, which is an affiliate of Novartis. In most of these markets, Vivelle® is marketed under the brand name Menorest®, Vivelle-Dot is marketed under the brand name Estradot and CombiPatch® is marketed under the brand name Estalis®.

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

Novartis is entitled to an annual $6.1 million preferred return, which has the effect of reducing our share of Novogyne s income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne s income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne s income was $17.6 million, $17.1 million and $14.4 million in 2004, 2003 and 2002, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne s Management Committee. Accordingly, the amount of cash that we receive from

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Novogyne in any period may not be the same as the amount of income we recognize from Novogyne for that period. In 2004, 2003 and 2002, we received $18.1 million, $21.7 million and $11.7 million in cash distributions from Novogyne, which accounted for a substantial portion of our net cash flows provided by operating activities for these periods. We expect that a significant portion of our earnings and cash flow for the next several years will be generated through our interest in Novogyne, but we cannot assure that Novogyne will continue to be profitable or make cash distributions. Any failure by Novogyne to remain profitable or to continue to make distributions could have a material adverse effect on our results of operations and financial condition.

The market for HT products, including our transdermal HT products, has contracted since the July 2002 publication of the WHI study that found adverse health risks associated with HT products. Comparing the second quarter of 2002 (the quarter immediately preceding the publication of initial data from the WHI study) to the fourth quarter of 2004, total prescriptions dispensed in the HT market in the United States decreased by 49%. For the same period, aggregate prescriptions for Noven s United States HT products decreased 12%. The estrogen segment of the HT market in the United States declined 44%, while our Vivelle® line of products decreased 3%. Vivelle-Dot, which represented 82% of our total United States prescriptions in the fourth quarter of 2004, increased 20% from the second quarter of 2002 to the fourth quarter of 2004. We believe Vivelle-Dot patch prescriptions have benefited from patient conversions from the original Vivelle® product.

United States prescriptions for our CombiPatch® product (which represented approximately 13% of our total United States prescriptions in the fourth quarter of 2004) declined 48% from the second quarter of 2002 to the fourth quarter of 2004, while prescriptions for the total United States market for fixed combination hormone therapy decreased 68%. The combination therapy arm of WHI involved an oral combination estrogen/progestin product and, accordingly, the combination therapy segment of the HT market has experienced the most significant decrease. Further decreases for our CombiPatch® product (whether as a result of the WHI studies, the production issues discussed below or otherwise) could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to these marketing rights, which would adversely affect the results of operations of both Noven and Novogyne. See Critical Accounting Policies Investment in Novogyne.

Certain Items that Affect Historical or Future Comparability

Production Issues

We maintain in-house product stability testing for our commercialized products. This process includes, among other things, testing samples from commercial lots under a variety of conditions to confirm that the samples remain within required specifications for the shelf life of the product.

In 2003, our product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot patches did not maintain required specifications throughout the products shelf lives, resulting in product recalls of certain lots. As a result, in 2003, Noven and Novogyne established allowances for the return of recalled product, which had the effect of reducing Noven s and Novogyne s net revenues by $1.4 million and $6.5 million, respectively, for the year ended December 31, 2003. Based on a review of available relevant information, including actual product returns and future expected returns, Noven and Novogyne reduced these allowances during the year

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ended December 31, 2004, which had the effect of increasing net revenues for the year ended December 31, 2004 by $0.6 million and $3.3 million for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase Noven s income before income taxes by $2.2 million for the year ended December 31, 2004. The effect on Novogyne of Novogyne s adjustment was to increase Novogyne s income before income taxes by $2.8 million for the year ended December 31, 2004. At December 31, 2004, Noven s allowances for recall related returns and reserves for expected costs related to the 2003 product recalls were immaterial. There are no remaining allowances at Novogyne related to the 2003 recall.

As a result of the 2003 recall of Vivelle-Dot patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of Vivelle-Dot. In the first quarter of 2005, a total of ten lots of Vivelle-Dot manufactured in 2003 were identified for recall when one of our stability protocols revealed that these lots did not meet required specification or were associated with lots that did not meet specification. Because these lots were manufactured in 2003, we estimate that an immaterial number of patches from these lots currently remain in distribution. Marketing, general and administrative expense in 2004 includes an allowance of $0.3 million for estimated costs related to these recalls.

Based on testing and analysis to date, Noven believes that the probable cause of the recent Vivelle-Dot stability failures remains related to the same problematic patch backing material that led to the 2003 recall. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot stability failures. If the root cause determination or additional testing (including Noven s routine stability testing) indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. The final field alert for the recall of the additional lots of Vivelle-Dot was submitted to the FDA on March 11, 2005, and we cannot predict what action, if any, the FDA may take as a result of the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, Novartis, as the holder of the Vivelle-Dot regulatory application, possesses the sole authority to initiate a recall and Novartis decision is not within our control. Among others risks, the recent, or any additional, recalls of Vivelle-Dot could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot. Vivelle-Dot represented over 80 percent of the total prescriptions written for Noven s products in the fourth quarter of 2004 and Noven s and Novogyne s results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

As previously disclosed, in late October 2004, our product stability testing program indicated that one commercial lot of CombiPatch® product did not maintain required specifications throughout the product s shelf-life due to the formation of crystals. This issue is unrelated to the issue that led to the 2003 CombiPatch® recall referenced above. Novartis has recalled the affected lot. The recall of this lot did not have a material impact on Noven s and Novogyne s financial statements for the year ended December 31, 2004. We continue to manufacture and ship CombiPatch® to Novogyne. We continue to maintain our stability testing for CombiPatch®, and are undertaking additional testing related to the October 2004 stability failure. If our testing indicates that additional CombiPatch® lots do not meet specifications or are affected by the issue impacting the lot recalled, there could be additional recalls. Although Noven and Novartis work together in assessing production issues, the decision to recall product resides with Novartis as the holder of the CombiPatch® regulatory application and is not

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within our control. If our estimates concerning product returns associated with the recall are incorrect, or if our continued testing indicates that more than one lot is affected, or if Novartis should initiate additional recalls for any reason, then Noven s and Novogyne s business and results of operations could be materially and adversely impacted.

The recent recalls may result in an FDA inspection of our facilities and procedures and we cannot assure that the FDA will be satisfied with our operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that our manufacturing controls and procedures are not sufficient, we could be required to suspend production until we demonstrate to the FDA that our controls and procedures are sufficient.

Shire

We are developing a transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder. Global rights to the developmental product were licensed to Shire in the first quarter of 2003 for payments up to $150.0 million, including $25.0 million paid at closing of the license transaction. In April 2003, we received a not approvable letter from the FDA relating to our New Drug Application (NDA) for our methylphenidate patch. Beginning in the third quarter of 2003, we ceased amortization of the unamortized balance of license revenue received in the Shire transaction due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in pursuing approval of our methylphenidate patch.

In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire are proceeding with the development of our methylphenidate patch. Development efforts include additional clinical studies, including another Phase III study. Pursuant to the agreements between the parties, Shire is managing these studies and Noven has committed to fund them. Noven s direct costs incurred in pursuit of approval are being deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven s research and development expenses in 2004 and are not expected to impact research and development expenses in 2005, although the direct expenses incurred in pursuit of FDA approval will reduce Noven s cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of December 31, 2004, the amount of deferred revenues was $5.7 million (which excludes the $5.0 million of deferred revenues related to Shire s repurchase right) and Noven does not expect its prospective cost in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for our methylphenidate patch.

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Results of Operations

Revenues:

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

	2004	% Change	2003	% Change	2002
Product revenues Novogyne:					
Product sales	$ 18,798	18%	$ 15,932	(37%)	$ 25,394
Royalties	5,204	5%	4,978	10%	4,505
	24,002	15%	20,910	(30%)	29,899
Product revenues third parties:					
Product sales	12,327	(23%)	16,078	(20%)	20,126
Royalties	542	323%	128	(26%)	174
	12,869	(21%)	16,206	(20%)	20,300
Total product revenues	36,871	(1%)	37,116	(26%)	50,199
Contract and license revenues:					
Contract	5,021	148%	2,024	13%	1,787
License	3,999	(1%)	4,026	19%	3,386
	9,020	49%	6,050	17%	5,173
Net revenues	$ 45,891	6%	$ 43,166	(22%)	$ 55,372

Net Revenues

As described in more detail below, the increase in 2004 revenues as compared to 2003 was primarily attributable to higher contract revenue due to the attainment of certain product development milestones and an increase of product sales in the United States to Novogyne. In addition, net revenues for the 2004 period also benefited from a reduction in allowances for returns. These increases were partially offset by a decline in sales of our international products.

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

Product Revenues Novogyne

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

The $3.1 million increase in revenues from Novogyne for 2004 as compared to 2003 primarily relates to $3.3 million in higher sales of Vivelle-Dot. The increase in Vivelle-Dot sales was primarily due to inventory reduction initiatives in the first half of 2003 intended to align inventories with post-WHI demand, which reduced our sales to Novogyne during the 2003 period. In addition, product revenues in 2003 included a $1.4 million allowance for returns related to product

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recalls. Based upon our review and analysis of historical and expected future returns, we reduced this allowance by $0.6 million in 2004. The net effect of these two events accounts for $2.0 million of the increase in net revenues for 2004 as compared to 2003. These increases are offset by a $0.8 million decrease in CombiPatch® product revenues, which reflect the continuing decline in prescription trends following the publication of the combination therapy arm of the WHI study and other studies. Price was not a factor contributing to the overall increase.

The decline in revenues from Novogyne for 2003 as compared to 2002 relates to volume declines of product sold to Novogyne, which reflect lower prescription trends following the publication of the WHI and other HT studies and the impact of inventory reduction initiatives in 2003 intended to align inventories with post-WHI demand. A $1.4 million allowance for returns related to product recalls established in 2003 also contributed to the decline. Price was not a factor contributing to this decline.

Product Revenues Third Parties

Product revenues third parties consists primarily of sales of Menorest, Estradot and Estalis® to Novartis Pharma at a price based on a percentage of the licensee s net selling price (subject to certain minima) for resale primarily outside the United States and Japan, together with royalties generated from Novartis Pharma s sales of Vivelle® and Estradot in Canada.

The $3.3 million decline in product revenues from third parties for 2004 as compared to 2003 primarily related to $5.5 million in lower unit sales of all products other than Estradot. The decline in sales reflected lower prescription trends following the publication of the combination therapy arm of the WHI study and other studies. In addition, Novartis Pharma has indicated that it has reduced orders for Menorest in certain countries in anticipation of planned transitions to Estradot. These declines were partially offset by $1.7 million in higher sales of Estradot and an increase of $0.4 million in royalties generated from Novartis Pharma s sales of Vivelle® and Estradot in Canada. The higher sales of Estradot is related to an increase of $1.1 million in price adjustment payments in 2004, which were recorded upon determining that Novartis Pharma s sales price of Estradot entitled Noven to receive amounts in excess of the minimum transfer price. The remaining increase in Estradot is mostly attributable to higher unit sales.

Revenues from third parties declined $4.1 million for 2003 as compared to 2002, of which $2.7 million related to volume declines of all products for the reasons discussed above and $1.4 million related to price declines, primarily of Estalis®.

Contract and License Revenues

Contract revenues consists of the recognition of payments received as work is performed on research and development projects. The payments received may take the form of non-refundable up-front payments, payments received upon the completion of certain phases of work and success milestone payments. License revenues consist of the recognition of up-front, milestone and similar payments under license agreements.

The increase in contract revenues for 2004 as compared to 2003 is primarily attributable to $4.4 million earned in 2004 in connection with our P&G Pharmaceuticals collaboration. Of the $4.4 million, $3.0 million was earned in the fourth quarter of 2004 and related to the attainment of a product development milestone as determined by P&G. License revenues were consistent in 2004

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and 2003, which reflects a decrease due to the recognition of license revenues in connection with the Shire transaction in 2003, which was not repeated in the current year. Beginning in the third quarter of 2003, we ceased amortization of the deferred balance of license revenues received in the Shire transaction due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in seeking approval of our methylphenidate patch. In the fourth quarter of 2003, we began to defer and offset our direct costs incurred in pursuit of approval (which totaled $13.4 million in 2004) against a portion of the $25 million deferred revenue previously received from Shire. The decrease in license revenues recognized from the Shire transaction during 2004 was partially offset by license revenue recognized in 2004 in connection with our Endo collaboration.

The increase in contract revenues for 2003 as compared to 2002 is primarily attributable to the attainment of certain product development milestones and the completion of certain product development contracts in 2003. The increase in license revenues for 2003 as compared to 2002 is due to the recognition of license revenues in connection with the Shire transaction. As noted above, we ceased amortization of the deferred balance of license revenues received in the Shire transaction at the beginning of the third quarter of 2003. In the fourth quarter of 2003, we began to defer and offset against the deferred revenue balance our direct expenses incurred in seeking regulatory approval for our methylphenidate patch (including the costs of any clinical studies), which totaled $0.4 million in 2003.

Gross Margin:

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

	2004	% Change	2003	% Change	2002
Total product revenues	$ 36,871	(1%)	$ 37,116	(26%)	$ 50,199
Cost of products sold	20,101	3%	19,482	(15%)	22,973
Gross profit (product revenues less cost of products sold)	16,770	(5%)	17,634	(35%)	27,226
Gross margin (gross profit as a percentage of product revenues)	45%		48%		54%
Changes in deferred profit on sales of product to Novogyne	(254)	(78%)	(1,140)	(336%)	483
Gross margin excluding impact of deferred profit	45%		44%		55%

Noven s cost of products sold is affected by deferred profits on Noven s sale of products to Novogyne. As a result of our 49% equity investment in Novogyne, we are required to defer 49% of our profit on product that we sell to Novogyne until that product is sold by Novogyne to trade customers. Since our cost of products sold is adjusted to reflect changes in deferred profit, our gross margin can vary from period to period based on the timing of our shipments to Novogyne and Novogyne s sale of our products to trade customers. If Novogyne sells more product than we provide it in a given period (i.e., if Novogyne s inventories decline), we will defer less profit from Novogyne. The amount of deferred profit has fluctuated significantly in the past three years, particularly in 2003 when Novogyne reduced its inventory of our HT products after the publication of the WHI studies. In light of the significant historic fluctuations in our deferred profit on sales of

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product to Novogyne, we have included our gross margin net of the changes in deferred profit on sales of product to Novogyne, which, Noven s management believes for the reasons described above, is more meaningful and useful to an understanding of Noven s gross margin.

The increase in gross margin excluding the impact of deferred profit in 2004 as compared to 2003 was primarily related to the $2.0 million net effect of reductions in 2004 of allowances for returns established in the prior year related to product recalls, an increase of $1.1 million in price adjustment payments received in 2004 and a $0.6 million increase in product royalties. All of these items increased product revenues without affecting cost of products sold. These factors causing gross margin to increase were partially offset by lower overhead absorption due to a decline in product sales coupled with an increase in overall overhead costs to accommodate expansion for future products.

The decline in gross margin excluding the impact of deferred profit in 2003 as compared to 2002 was related to lower overhead absorption due to a $13.5 million decline in product sales coupled with slightly higher overhead costs. An unfavorable geographic mix also contributed to the decline. Product sales to Novogyne declined $9.5 million, while product sales to third parties declined $4.0 million. The majority of product sales to Novogyne are comprised of United States product, which have a higher gross margin than foreign product, which makes up the majority of product sales to third parties. Gross margin excluding the impact of deferred profit in 2003 was also adversely affected by allowances for returns established in 2003 related to product recalls, which decreased product revenues without affecting cost of goods sold. These factors that caused gross margin to decline were partially offset by a $0.4 million increase in royalties.

Including deferred profit on sales of product to Novogyne in the calculation of gross margin would increase gross margin by 0% and 4% in 2004 and 2003 and would decrease gross margin by 1% in 2002.

Operating Expenses:

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

	2004	% Change	2003	% Change	2002
Research and development	$ 9,911	23%	$ 8,082	(31%)	$ 11,634
Marketing, general and administrative	17,271	9%	15,858	11%	14,257

Research and Development

The $1.8 million increase for 2004 as compared to 2003 was primarily attributable to a $1.5 million increase in non-clinical development expenses related to our fentanyl transdermal system and a $1.2 million increase in development expenses for HT products. In addition, there was a $0.7 million increase in personnel costs related to increased regulatory and clinical development activities for fentanyl and other developmental products. This increase was partially offset by a $1.8 million reduction in development and clinical expenses related to our methylphenidate patch. Beginning in the fourth quarter of 2003, our direct costs incurred in pursuit of approval of our methylphenidate patch are being deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Accordingly, those expenses are not reflected in our reported research and development expenses.

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The $3.6 million decline for 2003 as compared to 2002 was primarily attributable to $2.9 million lower expenses for our methylphenidate patch due to the completion of a Phase III clinical trial in 2002.

Marketing, General and Administrative Expenses

The $1.4 million increase in 2004 as compared to 2003 was primarily attributable to a $1.3 million increase in compensation and employee benefit costs attributable to expansion for anticipated new product launches and a $1.5 million increase in consulting, professional, legal, accounting and audit fees, a substantial portion of which relates to new internal control requirements resulting from the Sarbanes-Oxley Act and other regulatory requirements. This increase was partially offset by a reduction of $1.2 million in pre-launch marketing expenses for our methylphenidate patch, which ceased in early 2003 as a result of the license of this product to Shire, as well as a $0.6 million reduction in recall related expenses.

The $1.6 million increase in 2003 as compared to 2002 was primarily attributable to $0.9 million in costs associated with product recalls, a $0.7 million increase in insurance costs, a $0.4 million increase in legal fees, primarily related to the Shire transaction, and a $0.7 million increase in consulting, professional, accounting and audit fees primarily related to new internal control requirements resulting from the Sarbanes-Oxley Act and other regulatory requirements. This increase was partially offset by a reduction of $1.3 million in pre-launch marketing expenses for our methylphenidate patch, which ceased in early 2003 as a result of the Shire transaction.

Other Income and Expenses:

Income Taxes

Our effective tax rate was 34.9% for 2004 and 36.0% for 2003 and 2002. The provision for income taxes is based on the Federal statutory and state income tax rates. The decrease in our effective tax rate for 2004 as compared to the prior year relates primarily to a reduction in accruals for outstanding Internal Revenue Service audits. From time to time, we are subject to audits by taxing authorities covering a wide range of matters, and the Internal Revenue Service is currently auditing our federal income tax returns for certain open years. Such matters are subject to various uncertainties, and it is possible that some of these matters may be resolved unfavorably to us. Since 2001, we have established accruals for pending matters that we believe are probable and reasonably estimable. In the fourth quarter 2004, the provision for income taxes benefited from a $0.4 million reduction in these accruals for ongoing tax audits due to the favorable resolution of certain tax matters. As of December 31, 2004, we had $1.1 million in accruals related to these matters. Management believes that any liability that may ultimately result from the resolution of pending matters in excess of the amount accrued will not have a material adverse effect on our financial position, results of operations or cash flows.

Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of December 31, 2004, we had a net deferred tax asset of $14.9 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe it is

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more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

Equity in Earnings of Novogyne

We share in the earnings of Novogyne, after satisfaction of an annual preferred return of $6.1 million to Novartis, according to an established formula. Novogyne produced sufficient income in each of 2004, 2003 and 2002 for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne s earnings as Equity in earnings of Novogyne on our Statements of Operations.

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

	2004	% Change	2003	% Change	2002
Gross revenues	$ 124,791	4%	$ 120,282	(8%)	$ 130,235
Sales allowances	13,154	17%	11,279	(16%)	13,478
Sales returns allowances	6,224	(21%)	7,926	(44%)	14,272
Sales and returns allowances	19,378	1%	19,205	(31%)	27,750
Net revenues	105,413	4%	101,077	(1%)	102,485
Cost of sales	21,576	0%	21,485	(18%)	26,136
Gross profit	83,837	5%	79,592	4%	76,349
Gross margin percentage	80%		79%		74%
Selling, general and administrative expenses	35,624	16%	30,673	(7%)	33,091
Amortization of intangible asset	6,179	0%	6,179	0%	6,179
Income from operations	42,034	(2%)	42,740	15%	37,079
Interest income	191	5%	182	(48%)	350
Net income	$ 42,225	(2%)	$ 42,922	15%	$ 37,429
Noven s equity in earnings of Novogyne	$ 17,641	3%	$ 17,094	19%	$ 14,368

Novogyne Revenues

Novogyne s gross revenues increased $4.5 million for 2004 as compared to 2003, primarily due to $10.3 million in increased sales of Vivelle-Dot and $1.1 million in increased sales of Estradot to Canada, partially offset by a $2.2 million decrease in volume sales of Vivelle®, our first generation estrogen patch, and a $4.6 million decrease in volume sales of CombiPatch®. We believe the increase in Estradot sales to Canada was due to Novartis Pharma stocking inventory as they transitioned from Vivelle®, our first generation product, to Estradot, our second generation product. Approximately $7.8 million of the Vivelle-Dot increase was due to price increases, while the remaining $2.5 million increase related to increased unit sales based on increased prescription trends. The decline in volume sales of Vivelle® for 2004 as compared to 2003 is primarily attributable to Vivelle® being in a declining trend due to product maturity. The lower volume sales of CombiPatch®

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in 2004 were due to a continuing decline in the market for combination therapies after the publication of the combination therapy arm of the WHI study.

Novogyne s gross revenues declined $10.0 million for 2003 as compared to 2002, as a result of a $21.8 million decrease in volume sales of Vivelle® and CombiPatch®, partially offset by increased volume sales and price for Vivelle-Dot. The decline in volume sales of Vivelle® and CombiPatch® in 2003 as compared to 2002 was attributable to the same factors described above for 2004 compared to 2003. Inventory reduction initiatives did not have a material impact on results for 2003 as compared to 2002.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 11%, 9% and 10% of gross revenues for the year ended December 31, 2004, 2003 and 2002, respectively.

Sales returns allowances consist of: (i) changes in allowances for returns of expiring product, and (ii) changes in allowances for returns for product recalls. The activity for sales returns allowances for the fiscal years ended December 31, 2004, 2003 and 2002 was as follows:

	2004	2003	2002
Changes in allowances for returns of expiring product	$ 9,569	$ 1,426	$ 14,272
Changes in allowances for returns for product recalls	(3,345)	6,500	
Sales returns allowances	$ 6,224	$ 7,926	$ 14,272
Actual returns for expiring product	(8,675)	(5,931)	(8,165)
Actual returns for product recalls	(2,620)	(535)	
Actual returns during the year ended	$ (11,295)	$ (6,466)	$ (8,165)
Balance of sales returns allowances at December 31,	$ 9,169	$ 14,240	$ 12,780

The increase in allowances for returns of expiring product for 2004 as compared to 2003 is primarily related to higher expected returns as a result of increased sales of Vivelle-Dot as well as higher actual returns of Vivelle® . The reduction in allowances for returns for product recalls in 2004 is based on a review of available relevant information, including actual product returns and future expected returns for the CombiPatch® and Vivelle-Dot recalls.

The decline in allowances for returns of expiring product for 2003 as compared to 2002 is primarily attributable to increases in allowances for returns of expiring product in 2002 as a result of the publication of the WHI study and higher actual product returns in 2002. In 2003, product sales and actual returns of expired product declined, resulting in substantially lower allowances for returns of expiring product. The allowances for returns for product recalls in 2003 were related to the CombiPatch® and Vivelle-Dot recalls during that year.

Novogyne Gross Margin

Gross margin percentage was stable for 2004 as compared to 2003. The increase in gross margin for 2003 as compared to 2002 was primarily due to lower sales allowances and returns for

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expiring product, which increased net revenues without affecting cost of sales, and lower inventory obsolescence reserves.

Novogyne Selling, General and Administrative

Novogyne s selling, general and administrative expenses increased for 2004 as compared to 2003, due to increased sales force costs, higher advertising and promotion expenses, $1.0 million higher products liability insurance and $1.6 million in HT litigation reserves established in the fourth quarter of 2004, which are partially offset by a $0.7 million estimated insurance recovery. These increases were partially offset by decreased administrative expenses as a result of implementing a new sales force automation system and reduced sample expenses which was primarily attributable to timing of sample orders by Novogyne.

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

Liquidity and Capital Resources:

As of December 31, 2004 and 2003, we had $94.0 million and $83.4 million in cash and cash equivalents and working capital (current assets less current liabilities) of $97.3 million and $76.7 million, respectively.

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

	2004	2003	2002
Cash flows:			
Operating activities	$ 11,869	$ 29,104	$ 11,787
Investing activities	(7,115)	(4,722)	(3,011)
Financing activities	5,823	315	519

Operating Activities:

Net cash provided by operating activities in 2004 primarily resulted from the receipt of an $8.0 million license payment upon the closing of the Endo transaction in February 2004 and $18.1 million in distributions from Novogyne. The increase was partially offset by changes in working capital due to the timing of payments and receipts, specifically for payment of income taxes, expenses incurred in pursuit of regulatory approval for our methylphenidate patch, purchases of inventory for our fentanyl product, and amounts due from Novogyne.

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

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

Investing Activities:

Net cash used in investing activities in 2004, 2003 and 2002 was primarily attributable to the purchase of fixed assets to expand production capacity for future products and payment of patent development costs.

Financing Activities:

Net cash provided by financing activities in 2004 was attributable to $5.9 million received in connection with the issuance of common stock from the exercise of stock options.

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

Net cash provided by financing activities in 2002 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 capital leases.

Short-Term and Long-Term Liquidity:

Our principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under development and license agreements and distributions from Novogyne. For the year ended December 31, 2004, substantially all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. Accordingly, our net income may not be reflective of our short-term liquidity. Although we expect to receive distributions from Novogyne, there can be no assurance that Novogyne will have sufficient profits or cash flow to pay distributions or that Novogyne s Management Committee will authorize such distributions.

Our short-term cash flow is dependent on sales, royalties and license fees associated with transdermal HT products. Any decrease in sales of those products by us or our licensees or any increase in returns of products to Novogyne (including any such changes resulting from the HT studies), the further decline of the HT market, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term liquidity and require us to rely on our existing cash balances or on borrowings to support our operations and business.

We also expect our funding of additional studies for our methylphenidate patch will have a negative impact on our short-term liquidity. For the year ended December 31, 2004, $13.4 million in deferred license revenues were used to offset development expenses related to our methylphenidate patch, of which $10.6 million remained payable to Shire as of December 31, 2004. In early 2005, we received invoices for approximately $10.0 million of this amount. We expect to pay Shire the full $10.6 million in the first half of 2005. We cannot assure that our methylphenidate patch will be approved by the FDA, particularly in light of the not approvable letter we received from the FDA in April 2003, and there is no assurance that the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to our methylphenidate patch NDA. Additionally, even if the FDA approves our methylphenidate patch,

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we cannot assure that Shire will generate sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire with respect to our methylphenidate patch or that we will be able to recover those expenses through sales of the product.

As of December 31, 2004, we have incurred $10.8 million for the cost of pre-launch inventories for our fentanyl patch. If approval is not ultimately received or is delayed, our agreement with Endo provides that the parties will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula and we may be unable to recover our share of such costs, which could be up to approximately $6.0 million. If the product has not been approved by July 2005, Endo may have the right to terminate the license, depending on the number of generic competitors in the market.

Capital expenditures were $6.5 million in 2004, primarily to fund plant and equipment purchases for the manufacture of our fentanyl patch. We expect that our capital expenditures will increase significantly in 2005 as we continue to expand our manufacturing and storage facilities for products under development, including those under development with Shire, P&G Pharmaceuticals and others. We expect to fund these capital expenditures from our existing cash balances. As a general matter, we believe that we have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements.

In February 2005, we entered into an Industrial Long-Term Lease (the Lease) for approximately 73,000 square feet of newly constructed space located in close proximity to our manufacturing facility in Miami, Florida. We intend to use the leased space for the storage and, as needed, the manufacture of new product. The lease term is 10 years, which may be extended for up to an additional 21 years pursuant to four renewal options of five years each and a one-time option to renew for one year. The annual base rent is $6.40 per square foot. We also pay a monthly management fee equal to 1.5 percent of the base rent. The rent for the first year is discounted to $3.20 per square foot. The base rent is subject to annual increases of three percent during the initial 10 year term. After the initial term, the rent will be 95 percent of the fair market rate of the leased space as determined under the Lease. The landlord will reimburse us up to $912,300 for leasehold improvements. For accounting purposes, we expect to amortize the aggregate expected rental payments on a straight-line basis over the initial 10 year term of the Lease. The renewal terms have not been included for amortization purposes because we cannot reasonably estimate the rental payments after the initial term and we cannot assure that we will renew the Lease after the initial term. Any leasehold improvements will be recorded at cost and will be amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the initial 10 year lease term. Reimbursements of leasehold improvements by the landlord will be recorded as a deferred rent credit and will be amortized on a straight-line basis over the initial 10 year lease term as a reduction of rent expense.

For our long-term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as direct sales of our own products. We expect that our cash requirements will continue to increase, primarily to fund plant and equipment purchases to expand production capacity for new products. If our products under development, including those being developed with Shire, P&G Pharmaceuticals and others, are

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successful, these expenditures, which may include an additional manufacturing plant, are expected to be significant.

We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed under Factors Affecting Our Business and Prospects.

To the extent that capital requirements exceed available capital, we will seek alternative sources of financing to fund our operations. No assurance can be given that alternative financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory alternative financing, we may be required to delay or reduce our proposed expenditures, including expenditures for research and development and plant and equipment, in order to meet our future cash requirements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Aggregate Contractual Obligations

The table below lists our significant contractual obligations as of December 31, 2004 (all amounts are in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations[1]	$ 756	$ 391	$ 334	$ 31	$
Capital Lease Obligation[2]	250	125	125		
Purchase Obligations[3]	8,387	8,387			
Total[4]	$ 9,393	$ 8,903	$ 459	$ 31	$

[1]During the ordinary course of business, we enter into operating leases for machinery, equipment, warehouse and office space. Total rental expense for operating leases was $0.5 million, $0.3 million and $0.3 million for the years ended December 31, 2004, 2003 and 2002, respectively.

[2]During 2004 we entered into a capital lease obligation in the amount of $0.3 million for new equipment.

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

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

Also not included in the foregoing table is an operating lease entered into after December 31, 2004 with respect to approximately 73,000 square feet of industrial space. For description of this lease, see Short-Term and Long-Term Liquidity.

New Accounting Standards

In December 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46R, Consolidation of Variable Interest Entities (FIN 46). This Interpretation of Accounting Research Bulletin 51, Consolidated Financial Statements , addresses consolidation by business enterprises of variable interest entities which have one or both of the following characteristics: (i) the equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. We have applied this statement for our calendar year beginning January 1, 2004. Our investment in Novogyne is not considered a variable interest in a Variable Interest Entity (VIE) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to us and the adoption of this interpretation has had no impact on our financial statements. These conclusions are based on currently available information and require us to assess our investment interest and ownership rights in Novogyne. If our conclusions or our underlying assumptions of factual information concerning our investment in Novogyne were to change, Novogyne may be considered a VIE and our investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. We believe that even if a determination were made that Novogyne was a VIE at December 31, 2004, Novartis is the primary beneficiary due to its preferred return and 51% equity interest in Novogyne and would continue to consolidate Novogyne.

In November 2004, the FASB issued Statement of Financial Accounting Standard No. 151 Inventory Costs an amendment of ARB No. 43, Chapter 4 (SFAS 151) to clarify the accounting for abnormal amounts of idle facility expense, freight, or wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the so abnormal criterion outlined in Accounting Research Bulletin 43, Chapter 4, Inventory Pricing . SFAS 151 also introduces the concept of normal capacity and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We are currently assessing SFAS 151 and we are unable to currently estimate the impact it will have on our results of operations and financial condition.

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In December 2004, the FASB issued Statement of Financial Accounting Standard No. 123(R) Share-Based Payment (Revised 2004) (SFAS 123(R)) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award, which is generally over the vesting period. SFAS 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation , and supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees . For public companies such as Noven, the statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. We anticipate applying this statement for our third quarter beginning July 1, 2005, which we expect will result in compensation expenses of approximately $3.9 million (not including tax effects) for the second half of 2005, based on option grants outstanding at December 31, 2004. The foregoing amount does not include compensation expense for any stock options that may be granted after January 1, 2005. See Critical Accounting Estimates Fair Value of Stock Options for a discussion on fair value option valuation models and assumptions used in making this estimate.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, the fair value of employee stock options, the determination of the net realizable value of the net deferred tax asset, estimates related to allowance for returns related to product recalls, accrued liabilities, income and other tax accruals, revenue recognition and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Many of our critical accounting estimates are those which we believe require the most subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain or which involve factors that may be beyond our control. Using different assumptions could result in materially different results. A discussion of our critical accounting estimates, the underlying judgments and uncertainties affecting their application and the likelihood that materially different amounts would be reported under different conditions or using different assumptions, is as follows:

Revenue Recognition:

Substantially all of our product revenues were derived from sales to our licensees, Novogyne, Novartis Pharma and its affiliates and Aventis Pharma AG. Certain of our license agreements provide that the ultimate supply price is based on a percentage of the licensee s net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price we are entitled to receive on sales to the licensee. We receive the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. We record any upward adjustments to revenues at the time that the information necessary

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to make the determination is received from the licensee. If the upward adjustments are not determinable, we record the adjustments on a cash basis (i.e. when received). These amounts are included in product revenues. If our licensee s determination that upward adjustments to revenues prove to be incorrect or inaccurate our results of operations and financial position may be materially impacted.

We enter into certain contracts that have various terms and conditions that may have multiple revenue characteristics, including license revenues, contract revenues, product sales and manufacturing revenues. As prescribed by EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables , we analyze each contract in order to separate each deliverable into separate units of accounting and then recognize revenues for those separated units at their fair value as earned in accordance with SEC Staff Accounting Bulletin Topic 13, Revenue Recognition (Topic 13). If each deliverable does not qualify as a separate unit of accounting, the deliverables are combined and the amounts under the contract are allocated to the combined deliverables. The appropriate recognition of revenue is then determined for the combined deliverables as a single unit of accounting. The analysis prescribed by EITF 00-21 requires us to make a number of significant assumptions and judgments, including those related to: sales price, unit costs and manufacturing profit: expected launch date of the product licensed and valuation of that licensed product; and price, cost, and applicable profit of research and development work to be performed. Changes in any of these assumptions and judgments could lead to a different conclusion on what the separate units of accounting are and their applicable fair values, which may lead to material changes to revenue recognition.

License revenues consist of up-front, milestone and similar payments under license agreements and are not recognized until earned under the terms of the applicable agreements. In most cases, license revenues are deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter. Estimates of product life cycles are inherently uncertain including as a result of regulatory, competitive or medical developments. We estimate product life cycles based on our assessment of various factors, including the expected launch date of the product licensed, the strength of the intellectual property protection of the product, and various other competitive, developmental and regulatory issues, and contractual terms. Any change to the actual or estimated product life could require us to change the recognition period.

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

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

additional payments upon completion of additional phases; and

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

For non-refundable up-front payments received prior to commencing work, we recognize revenue based on the proportionate share of the work performed by us in any given period based on the total hours we expect to incur on the project to deliver all our obligations under the contract.

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There are a number of assumptions, estimates and judgments that are involved in determining the total hours we expect to incur on the project, including personnel and time involved. Similar assumptions, estimates and judgments are involved in determining the proportionate share of the work performed by us in any given period in addition to estimates of hours remaining to complete the project. Any changes in these assumptions, estimates and judgments may cause us to materially change revenue recognition.

Additional payments upon completion of additional phases and milestone payments are recorded when the specified performance criteria are achieved, as determined by the customer. Each contract may have different payment terms and each customer may vary in its determination that specified performance criteria are achieved. Therefore, the timing of revenue recognition may vary from contract to contract.

Revenues are net of an allowance for returns. We establish allowances for returns for product that has been recalled or that we believe is probable of being recalled. The methodology used by us to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature of the assumptions and complexities inherent in this area and in the pharmaceutical industry. For example, during 2003 Novartis initiated recalls of certain lots of CombiPatch® and Vivelle-Dot due to production issues. Our revenues for 2003 are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively. Based on a review of available information, including actual product returns and future expected returns, Noven and Novogyne reduced these allowances during 2004, which had the effect of increasing net revenues for 2004 by $0.6 million and $3.3 million for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase Noven s income before income taxes by $2.2 million for 2004. The effect on Novogyne of Novogyne s adjustment was to increase Novogyne s income before income taxes by $2.8 million for 2004. If our estimate concerning the amount of the product returns is incorrect or if Novartis should initiate further unexpected recalls, then our results of operations could be materially different.

Fair Value of Stock Options:

We have elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations in accounting for our employee stock options as allowed pursuant to SFAS 123, as amended by SFAS 148. Accordingly, no compensation expense has been recognized for the years ended December 31, 2004, 2003 and 2002.

As noted in the section New Accounting Standards , in December 2004, the FASB issued SFAS 123(R) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. Had compensation cost for our stock option plans been determined on the basis of fair value at the grant date for awards under those plans, consistent with this statement and using our existing valuation method for our employee stock options, the Black-Scholes option pricing model, we estimate that our net income for the years ended December 31, 2004, 2003 and 2002 would have been reduced by 52%, 32% and 32%, respectively. Furthermore, as stated in the section New Accounting Standards , we anticipate applying this statement for our third quarter beginning July 1, 2005, which we expect would result in compensation expenses of approximately $3.9 million (not including tax effects) for the second half of 2005, based on option grants outstanding at December 31, 2004. The foregoing amount does not include compensation

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expense for any stock options that may be granted after January 1, 2005. However, these calculations use option valuation models that use highly subjective assumptions, including expected stock price volatility. Because our stock options have characteristics significantly different from traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable measure of the fair value of our employee stock options. In addition, the effect of applying the fair value method of accounting for stock options on reported net income for 2004, 2003 and 2002 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.

Inventories:

Inventories, which include material, labor and manufacturing overhead, are stated at the lower of cost (first-in, first-out method) or market. We use a standard costing system to estimate our FIFO cost of inventory at the end of each reporting period. Historically, standard costs have been substantially consistent with actual costs. We determine the market value of our raw materials, finished product and packaging inventories based upon references to current market prices for such items as of the end of each reporting period and record a write-down of inventory standard cost to market, when applicable. We periodically review our inventory for excess items, and we establish a valuation provision based upon the age of specific items in inventory and the expected recovery from the disposition of the items. A provision is established for the estimated aged surplus, spoiled or damaged products, and discontinued inventory items and components. The amount of the provision is determined by analyzing inventory composition, expected usage, historical and projected sales information, and other factors. Changes in sales volume due to unexpected economic or competitive conditions are among the factors that could result in materially different amounts for this item.

Income Taxes:

Accounting principles generally accepted in the United States require that we not record a valuation allowance against our net deferred tax asset if it is more likely than not that we will be able to generate sufficient future taxable income to utilize our net deferred tax asset. Although realization is not assured, we believe it is more likely than not that the net deferred income tax asset will be realized based upon our estimated future income and, accordingly, no valuation allowance for the net deferred income tax asset was deemed necessary. Subsequent revisions to the estimated net realizable value of the net deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

From time to time, we are subject to audits by taxing authorities, covering a wide range of matters, and the Internal Revenue Service is currently auditing our federal income tax returns for certain open years. Such matters are subject to various uncertainties, and it is possible that some of these matters may be resolved unfavorably to us. We have established accruals for pending matters that we believe are probable and reasonably estimable. We have made certain assumptions, estimates and judgments when establishing these accruals, including: estimates of settlements; interest on settlements, interest rates and applicable interest periods, and penalties. Changes to these assumptions, estimates and judgments could have a material impact on our provision for income taxes.

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Investment in Novogyne:

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

As of December 31, 2004, Novogyne had a long-term intangible asset of $38.6 million related to the acquisition of the marketing rights to CombiPatch®. Accounting principles generally accepted in the United States require that Novogyne record this asset at cost and that the asset be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. Testing for impairment requires Novogyne to estimate the undiscounted future cash flow of the asset and compare that amount to the carrying value of the asset. If this analysis indicates that a possible impairment exists (undiscounted future cash flows are less than the carrying value), Novogyne would be required to estimate the fair value of the asset. The determination of fair value of this asset would involve numerous uncertainties because there is no viable actively traded market for the marketing rights of a pharmaceutical product. As permitted by accounting principles generally accepted in the United States, if Novogyne would be required to estimate the fair value of the marketing rights, it would utilize a discounted cash flow analysis. A discounted cash flow analysis values an asset on the basis of the net present value of the cash expected to be generated by that asset over its estimated useful life. This analysis requires Novogyne to make a number of significant assumptions and judgments. For example, estimates need to be made regarding prescription trends, sales price, unit cost and product life cycle among many other factors including the discount rate to be applied to the estimated cash generated by sales of the product. A material change in any of these assumptions may require Novogyne to record an impairment loss, which would adversely affect Novogyne s operating results in the period in which the determination or allowance were made. This would reduce our earnings attributable to our investment in Novogyne for that period and the amount of our investment in Novogyne and could, depending on the size of the impairment, result in a loss at both the Novogyne and Noven level for the period in which the impairment occurred. Neither Novogyne nor we are able to predict the effect of the recently discontinued and currently ongoing HT studies, the recalls in 2003 and 2004 affecting CombiPatch®, or the recent launch of a competitive combination HT patch, on the prospects for the HT market or the market for CombiPatch®. Any adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in CombiPatch® which could require Novogyne to record an impairment loss for that asset.

Novogyne records sales net of sales allowances for chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts, product returns and other allowances. The returns portion of the sales allowance related to expiration dating is based in part on Novartis returned goods policy. The methodology used by Novogyne to estimate product returns is based on (i) the historical experience of actual product returns and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate. However, because Novogyne s return history includes periods of higher and lower trade inventory levels and varying levels of demand, in making its final estimations of expected product returns, Novogyne also considers trends and expectations for future demand and trade inventory levels. Novogyne does not accept returns due to short-dating until the product has less than a certain

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amount of shelf-life remaining. Also, Novogyne does not accept returns due to expiration later than a certain period after the product has expired. These policies cause a significant lag time between when a product is sold and the latest date on which a return could occur. Novogyne believes this is a reasonable basis on which to estimate returns exposure and incorporates the key factors that contribute to returns. In addition, Novogyne establishes sales returns allowances for product that has been recalled or that it believes is probable of being recalled. The methodology used to estimate product returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

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

In the course of its audit of Novogyne s financial statements included in this Annual Report on Form 10-K, Novogyne s independent registered public accounting firm identified what it believes is a significant deficiency in Novogyne s internal controls which related to oversights by Novartis in connection with Novogyne s accounting for certain rebate accruals. These oversights resulted in an immaterial adjustment at Novogyne in the fourth quarter of 2004. We have been advised that the Audit and Compliance Committee of Novartis AG has engaged outside counsel and is conducting an ongoing internal investigation of this matter. It is not possible for us to predict what impact, if any, Novartis internal investigation may have. To our knowledge, none of the issues that are the subject of the investigation involves Noven, Noven s accounting policies or practices, or any of Noven s officers, directors or employees.

Novogyne is required to establish accruals for certain loss contingencies related to litigation. Novogyne accrues estimated legal fees and settlement costs in accordance with SFAS No. 5, Accounting for Contingencies . However, the estimation of the amount to accrue requires significant judgment. Litigation accruals require Novogyne to make assumptions about the future outcome of each case based on current information, expected legal fees that will be incurred and any expected insurance recovery. As of December 31, 2004, Novogyne had litigation accruals of $1.6 million, with an expected insurance recovery of $0.7 million. Novartis controls and maintains the accruals associated with such litigation on behalf of Novogyne and pays all monies owed for legal fees and settlements, as well as collects any insurance recovery. The litigation accruals and estimated insurance recoveries are maintained by Novartis for its business as a whole and those accruals and recoveries relating to Novogyne are estimated by Novartis. Based on an analysis of the underlying data, the amounts recorded by Novogyne represent Novartis best estimate of litigation

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accruals and estimated insurance recoveries relating to Novogyne. However, neither Novogyne nor we can control Novartis analysis of the underlying data or its application of that analysis to Novogyne. Litigation and its outcome are inherently difficult to predict. If Novartis materially changes the assumptions it uses in allocating litigation accruals and any applicable insurance recoveries, or if actual outcomes are different from what has been estimated, Novogyne may be required to record additional charges or reduce its accruals, which would affect Novogyne s operating results during the period in which the determination, accrual or reduction were made, and would consequently affect the earnings attributable to our investment in Novogyne for that period.

The critical accounting estimates discussed herein are not intended to be a comprehensive list of all of our accounting estimates. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management s judgment in their application. There are also areas in which management s judgment in selecting any available alternative would not produce a materially different result.

Outlook

A summary of our financial guidance is provided below. This forward-looking information is based on our current assumptions and expectations, many of which are beyond our control to achieve. In particular, for purposes of this guidance we have assumed that during 2005 (except as otherwise indicated below) there will not be any material:

transactions;

changes in Noven s or Novogyne s accounting or accounting principles;

regulatory, technological or clinical study developments;

changes in the supply of, demand for, or distribution of our HT products (including any changes resulting from product recalls, competitive HT products, or new HT study results);

changes in our business relationships/collaborations; or

changes in the economy or the health care sector generally.

Financial guidance is inherently uncertain. Accordingly, we cannot assure that we will achieve results consistent with this guidance. If our assumptions or expectations concerning any of these matters prove to be incorrect, our actual financial results could differ materially from the expected results discussed below. For a discussion of certain factors that may impact our actual financial results for the periods referenced, readers should carefully consider the risks, uncertainties and cautionary factors discussed below under the caption Factors Affecting Our Business and Prospects.

Our financial guidance does not reflect the potential impact on Noven s results of SFAS 123(R), *Accounting for Stock Based Compensation*, which is scheduled to become effective beginning with our 2005 third quarter results. See Management s Discussion and Analysis of Financial Condition and Results of Operations New Accounting Standards.

Potential Fentanyl Revenues. Our ANDA for our generic fentanyl patch is currently pending at the FDA, and we are unable to predict when or if it will be approved. If our ANDA is approved and the product is launched by Endo (the licensee of the product in the U.S. and Canada), we expect to receive a launch-related milestone payment ranging from $5.0 million to $10.0 million, which

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payment will be deferred and recognized as Noven license and contract revenues over the remainder of the 10-year period that began on the closing of the Endo license transaction in the first quarter of 2004. Under the terms of our agreement with Endo, we will manufacture and supply Endo with finished product at our cost and will share in Endo s profit generated from U.S. product sales. At this time, we do not have sufficient information regarding timing of approval, number of competitors, market share, product pricing and other factors necessary to forecast an expected contribution of our fentanyl patch to our 2005 financial results.

Research and Development. In support of our strategy to expand our product pipeline, we expect to continue to invest in research and development in 2005 at levels comparable to 2004. In addition, we are working to formulate certain new transdermal products that, if successfully formulated, may enter human studies during 2005. These studies, if initiated, would be funded by Noven and may cause our research and development expense in 2005 to increase substantially over 2004 levels.

Marketing, General and Administrative Expense. We expect Noven s marketing, general and administrative expense in 2005 to increase over 2004 levels, with anticipated increases in costs associated with facility expansion, professional services fees and other areas.

Capital Expenditures. We expect that our capital expenditures will increase significantly in 2005 as we continue to expand our manufacturing and storage facilities for products under development, including those under development with Shire, P&G Pharmaceuticals and others.

Novogyne. Based on our current prescription forecasts, we believe that Novogyne s revenues and net income for full-year 2005 should approximate 2004 results.

Factors Affecting Our Business and Prospects

The following section summarizes certain risk factors that may cause our results to differ from the forward-looking statements made in this report or otherwise made by or on behalf of Noven. The risks and uncertainties described below are not listed in order of priority and are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operation. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

Additional HT studies may cause the market for our HT products to further decline.

The market for HT products has been negatively affected by the WHI study and other studies that have found that the overall health risks from the use of certain HT products exceed the benefits from the use of those products among healthy postmenopausal women. For example, total prescriptions dispensed in the HT market in the United States declined by 49% from the second quarter of 2002 (the quarter immediately preceding the WHI study) to the fourth quarter of 2004. The market for HT products, including ours, both in the United States and abroad, could be further adversely impacted if additional or follow-up HT studies find unacceptable risks from HT use. Currently, our liquidity, results of operations and business prospects are almost entirely dependent on sales, license royalties and fees associated with transdermal HT products. Accordingly, any further adverse change in the market for HT products could have a material adverse impact on our business, financial position and results of operations.

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Our failure to develop, license or acquire new products and commercialize them on a timely basis could negatively affect our financial position and results of operations and could cause the price of our common stock to decline.

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

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

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

We depend upon collaborative agreements with other pharmaceutical companies to obtain regulatory approval for and to market and sell certain of our products. To help alleviate the up-front financial burden of seeking product approval and commercializing products we often seek out strategic partners to whom we can license our products. Under the terms of the Novogyne joint venture, Novartis is responsible for the distribution of Novogyne s products, including Vivelle-Dot, and for selling Novogyne s products to its trade customers. For our methylphenidate patch, we have granted the exclusive marketing rights to Shire and we are working jointly with Shire to obtain FDA approval of our methylphenidate patch. For our transdermal fentanyl patch, we have granted the exclusive marketing rights to Endo. Failure of Novartis and our other marketing partners to market our products successfully would cause the quantity of products purchased from us and the amount of fees and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and operations. Our partners may have different and, sometimes, competing priorities. Some of our partners, including Novartis and Shire, market and sell products competitive

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with ours. Shire has a portfolio of ADHD products and in early 2005 licensed an amphetamine pro drug in phase III studies for the treatment of ADHD. The marketing organizations of our partners may be unsuccessful, or those partners may assign a lower level of priority to the marketing of our products. If one or more partners fails to pursue the marketing of our products as planned, or if marketing of any of those products is otherwise delayed, our business, financial position and results of operations may be negatively affected. Absent these marketing partners, we do not presently have a significant direct marketing channel to health care providers for our drug delivery technologies.

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

Our equity in earnings of Novogyne contributed substantially all of our income before income taxes in 2004, and Novogyne s results will likely continue to be material to us in the future. Because, among other things, we are vastly different in size from Novartis, and because Novartis and its affiliates sell competing products outside of Novogyne, our interests may not always be aligned. This may result in potential conflicts between Novartis and us on matters relating to Novogyne which we may not be able to resolve on favorable terms or at all. Under the Novogyne joint venture agreement, Novartis has the right to dissolve Novogyne under certain circumstances. Novogyne s Management Committee is comprised of a majority of representatives from Novartis. While certain significant corporate actions require the supermajority vote of the committee members, we do not control Novogyne. In addition, the joint venture operating agreement has a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Novartis is a larger company with greater financial resources, and therefore may be in a better position to be the purchaser if the provision is triggered. If the provision is triggered and Novartis is the purchaser, there can be no assurance that we would be able to reinvest the proceeds of the sale in a manner that would result in sufficient earnings to offset the loss of earnings from Novogyne. If the provision is triggered and we are the purchaser, there can be no assurance that we would not be adversely affected by the changes in capital and/or debt structure that likely would be required to finance the purchase transaction.

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

Under the Novogyne joint venture, Novartis is responsible for providing Novogyne with all financial, accounting, legal and regulatory services, including monitoring inventory levels and estimating and recording sales allowances and returns for Novogyne (which include reserves and allowances related to product returns). As a consequence, we may have limited ability to accurately forecast the amount of such sales allowances in any period. If Novartis materially changes the assumptions it uses in allocating reserves or in the actual determination of the gross reserve, Novogyne may be required to record an additional reserve allowance on its financial statements, which would adversely affect Novogyne s operating results during the period in which the determination or reserve were made, and would, consequently also reduce our earnings attributable to our investment in Novogyne for that period. Failure by Novartis to perform its obligations under the joint venture could negatively affect the financial position and results of operations of Novogyne and us. In the course of its audit of Novogyne s financial statements included in this Annual Report on Form 10-K, Novogyne s independent registered public accounting firm identified what it believes is a significant deficiency in Novogyne s internal controls which related to oversights by Novartis in connection with Novogyne s accounting for certain rebate accruals. These oversights resulted in an immaterial adjustment at Novogyne in the fourth quarter of 2004.

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We have been advised that the Audit and Compliance Committee of Novartis AG has engaged outside counsel and is conducting an ongoing internal investigation of this matter. It is not possible for us to predict what impact, if any, Novartis internal investigation may have. To our knowledge, none of the issues that are the subject of the investigation involves Noven, Noven s accounting policies or practices, or any of Noven s officers, directors or employees.

We may be unable to obtain marketing approval for our new products, including our methylphenidate patch and our fentanyl patch, on a timely basis or at all.

We are not able to market our products (including generic drug products) in the United States or other jurisdictions without first obtaining marketing approval from the FDA or an equivalent foreign agency. The process of obtaining FDA approval for a new product may take several years or more and is likely to involve the expenditures of substantial resources. The process is subject to the broad authority and discretion of the FDA. As a result of the publicity surrounding the withdrawal of Vioxx® by Merck & Co., Inc. in the fourth quarter of 2004 and the publicity surrounding HT products and anti-depressants such as Zoloft®, both citizen s group and interests in the United States Congress have called for investigation and possible reform of the FDA approval process and the FDA may impose more stringent standards in approving or monitoring new products compared to the standards applied in the past. We cannot predict what effect changes in regulations or legal interpretations, if, when and as promulgated may have on our business in the future.

In April 2003, we received a not approvable letter from the FDA relating to the NDA for our methylphenidate patch. Based on feedback resulting from a meeting with the FDA, Noven and Shire are proceeding with the development of our methylphenidate patch, including another Phase 3 study. If the additional studies are successful and completed on schedule, the parties expect to file an amendment to the pending NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for our methylphenidate patch. In addition to our methylphenidate patch, we are currently seeking regulatory approval for our fentanyl transdermal system for chronic pain. Our ANDA for this product was accepted for filing in October 2003 and is under review at the FDA. In January 2005, Shire s time-released amphetamine oral formulation (Adderall XR®) was withdrawn in Canada by regulators citing safety concerns. We cannot predict the impact, if any, this development may have on our developmental methylphenidate patch.

We cannot assure that we will obtain the necessary regulatory approval for these products or other products under development or that any such approval will be free from unduly burdensome conditions or limitations. In light of the WHI and other HT studies, it is possible that healthcare regulators could delay the approval of HT products as well as hormonal therapies for HSDD or require that any such new products be subject to more extensive or more rigorous study and testing prior to being approved, or could receive approval subject to more extensive conditions or limitations.

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

Even if we are able to obtain regulatory approval for our new products, the success of our products will depend on their market acceptance. Substantially all of our revenues are generated

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through sales of transdermal delivery systems, which generally are more expensive than oral formations. Our products are marketed primarily to physicians, some of whom are reluctant to prescribe a transdermal delivery system when an alternative delivery system is available. We and our licensees must demonstrate to prescribing physicians the benefits of transdermal delivery, especially with respect to products such as our methylphenidate patch for which there is presently no transdermal system on the market. The commercial success of our products is also based in part on patient preference, and difficulties in obtaining patient acceptance of our transdermal delivery systems may similarly impact our ability to market our products.

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

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

Our supply agreements with our licensees impose strict obligations on us with respect to the manufacture and supply of our products. Failure to comply with the terms of these supply agreements may result in our being unable to supply product to our licensees, resulting in lost revenues by us and potential responsibility for damages and losses suffered by our licensees. Our supply agreement for Vivelle® and Vivelle-Dot has expired. Since the expiration of the Vivelle® supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms. We cannot assure that we will enter into a new supply agreement on satisfactory terms or at all. It is not clear that the non-commercial terms of the supply agreement would be enforceable with respect to post-expiration events or occurrences. Due to our dependence on Novogyne, we may be unable to negotiate favorable business terms with them or resolve any dispute that we may be involved in with them in a favorable manner. Failure to continue operating in accordance with the supply agreement s commercial terms could have a material adverse effect on our business, results of operations and financial position. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

Our Products May Be Recalled

Product recalls or product field alerts may be initiated at our discretion (if we have regulatory authority for the product), at the discretion of our partners (if they have regulatory authority for the product), at the discretion of the FDA or at the discretion of other government agencies. Our products may be recalled for various reasons including the failure of our products to maintain their stability through their expiration dates, manufacturing issues, quality claims, safety issues, disputed labeling claims or other reasons. As discussed under the caption Production Issues in Item 7 of this report, our CombiPatch® and Vivelle-Dot products have been the subject of product recalls.

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The final field alert for the recall of 10 additional lots of Vivelle-Dot was submitted to the FDA on March 11, 2005 and we cannot predict what action, if any, the FDA may take with respect to the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, the decision to recall product resides with Novartis as the holder of the Vivelle-Dot regulatory application and is not within our control. Among others risks, the recent recalls of Vivelle-Dot, or any further impact of the issues causing these recalls, could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot™. Although we seek to mitigate the risk of product recalls, we cannot assure that there will not be recalls of our products in the future. We do not carry any insurance to cover the risk of a potential product recall. A significant product recall could materially affect our sales, the prescription trends for the products and the reputation of the product and Noven. In these cases, our business, results of operations and financial condition could be materially adversely affected.

We face scale-up risks in the manufacture of new products in commercial quantities.

Our methylphenidate patch and our fentanyl patch are new products that we have never manufactured on a commercial scale. Inefficiencies and other scale-up problems may occur in the process of manufacturing new products in commercial quantities. Failure of Noven to adequately and timely scale-up its manufacturing processes for new products or otherwise meet its supply requirements would adversely affect our revenues and could affect the success of our new product launches. It may also result in Endo, Shire or other collaboration partners relying more heavily on second manufacturing sources, thus reducing the manufacturing revenues that we would otherwise realize. It could also jeopardize our ability to obtain milestone payments under the Shire and Endo transactions. In addition, the active ingredients in our methylphenidate patch and our fentanyl patch are more expensive than the active ingredients in our HT patch products. If we experience manufacturing difficulties such as quality problems, yield deficiencies or similar issues, our overall manufacturing costs may be higher than anticipated.

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

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products. These regulations are wide-ranging and govern, among other things: adverse drug experience reporting, product promotion, product pricing and discounting, drug sample accountability, drug product stability, product manufacturing, including good manufacturing practices, and product changes or modifications. Our facilities handle controlled substances, resulting in additional extensive regulatory requirements and oversight. Compliance with the extensive government regulations applicable to our business requires the allocation of significant time, effort and expense. 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

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applications, and criminal prosecution. Under the terms of the Novogyne joint venture, Novartis is responsible for providing regulatory services. While we believe that Novartis provides these services adequately, there can be no assurance that a violation of any of these regulations will not have an adverse effect on us.

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

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

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

We face competition from a number of companies in the development of transdermal drug delivery products, and competition is expected to intensify as more companies enter the field. Some of these companies are substantially larger than we are and have greater resources than we do, as well as greater experience in developing and commercializing pharmaceutical products. As a result, they may succeed before us in developing competing technologies or obtaining governmental approvals for products. Our products compete with other transdermal products as well as alternative dosage forms of the same or comparable chemical entities, as well as non-drug therapies. We expect increased competition in the HT market as a result of the recent launches of a vaginal estrogen delivery system, a combination estrogen/progestin patch, an estrogen cream, an estrogen gel products, as well as the expected launch of an ultra-low dose estrogen patch. The ADHD market is very competitive and our receipt of the sales-based milestones under the Shire agreement depends on the sales levels achieved by Shire which already markets non-methylphenidate ADHD products. Other competitors marketing or developing ADHD products include Johnson & Johnson, Novartis, Glaxo-Smithkline, Bristol-Myers Squibb, Abbott Laboratories, Celltech plc, Cephalon, Inc. and Eli Lilly. Johnson &

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Johnson markets Concerta®, the market-leading methylphenidate product, and Novartis and Eli Lilly & Company (Lilly) market competitive ADHD products. Strattera®, a non-stimulant, non-controlled substance therapy, has gained significant market share since launched by Lilly in 2003. There is at least one clinical study underway comparing the efficacy of Strattera® to a long-acting methylphenidate product. If Strattera® or other therapies in development by other companies become recognized as therapeutically superior to stimulants, or are preferred by physicians, parents and/or patients, the market for our methylphenidate patch would be adversely affected. These competitive products, especially those already marketed by Shire and those not designated as controlled substances, may negatively impact Shire s ability to gain market share for our methylphenidate patch and therefore may decrease the likelihood that we will receive the sales-based milestone payments. If approved by the FDA, our fentanyl transdermal system will face a highly competitive market. Currently, the market consists of: (i) Duragesic®, the branded product, (ii) a product supplied by the branded manufacturer and sold as a generic by a third party, and (iii) a generic version of Duragesic®. In addition to our ANDA, we understand that several additional companies have submitted ANDAs for a transdermal fentanyl system. In the market for generics, the first products to be commercialized typically achieve significant market share. As competing generic manufacturers receive regulatory approvals, market share, revenues and gross profit of those companies already on the market typically decline, in some cases dramatically. Companies seeking to enter the market with newly approved products will generally seek to gain market share through price reductions and other customer incentives, which can have the effect of reducing pricing and market share for all competitors in the market. Accordingly, the level of market share, revenues and gross profit derived from our fentanyl patch will depend upon the timing of any FDA approval for our product, the number of competitors then in the market, and the timing of our launch in relation to competing approvals and launches.

We cannot assure that our products will compete successfully against competitive products or that developments by others will not render our products obsolete or uncompetitive. If we cannot maintain competitive products and technologies, our current and potential strategic partners may choose to adopt the drug delivery technologies of our competitors or their own internally developed technologies.

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

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

Competitors may also pursue legislative and other regulatory or litigation strategies to prevent or delay our launch of a generic product such as our developmental transdermal fentanyl system. These strategies include, but are not limited to: seeking to obtain new patents on drugs for which patent protection is about to expire, changing the labeling for the branded product, filing a citizen petition with the FDA, pursuing state legislative efforts to limit the substitution of generic

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versions of brand pharmaceuticals, filing patent infringement lawsuits that automatically delay FDA approval of many generic products, introducing a second generation product prior to the expiration of market exclusivity for the first generation product which may reduce demand for a generic first generation product, and obtaining market exclusivity extensions by conducting pediatric trials of brand drugs.

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

Pharmaceutical prices, including prices for our products, in Europe and certain other countries are significantly lower than in the United States. Because our agreements with Novartis Pharma provide for us to receive a percentage of Novartis Pharma s net selling price (subject to a minimum price), our gross margins are generally much lower for product sold to Novartis Pharma for resale outside of the United States than for product sold to Novogyne for sale in the United States. In addition, the lower prices restrict Novartis Pharma s gross margin realized from selling our products. Because our products compete for sales and marketing resources with other Novartis Pharma products, including competitive HT products, there can be no assurance that the relatively low gross margins generated from selling our products will not cause Novartis Pharma to focus its resources on other products or even not launch our products in certain countries. Novartis Pharma has launched the product in Germany, in Spain (without the benefit of government reimbursement) and in a number of smaller European countries. We have been advised that Novartis Pharma is in the process of launching the product through a marketing partner in the United Kingdom and France and is in negotiations with regulatory authorities in Italy with respect to the reimbursement for Estradot in Italy. We cannot assure that Novartis Pharma will be successful in launching Estradot in these or other countries. The profitability of sales in Europe may also be negatively affected by parallel trade practices in the European Union whereby a licensed importer may take advantage of price disparity between markets by purchasing our products in a market with a relatively lower price and then importing them into a country with relatively higher price. In addition, Novartis Pharma has advised us that they plan to seek marketing approval and commercialization of a lower dosage strength when and if a next generation combination product is developed. No assurance can be given that we will complete development of a next generation combination estrogen/progestin patch or that approval will be obtained, and the timing of any launch of a next generation combination estrogen/progestin patch product cannot be predicted. We expect that growth in this market will be limited unless and until a next generation combination estrogen/progestin patch product is developed, approved and launched.

Our quarterly operating results are subject to significant fluctuations.

In 2004, we experienced significant fluctuations in our quarterly operating results and we expect that revenues from product sales to our licensees as well as our research and development expenditures will continue to fluctuate from quarter to quarter and year to year depending upon various factors not in our control, including the purchasing patterns of wholesale drug distributors, marketing efforts of each licensee, fluctuations in sales and returns allowances, including those related to allowances for expiring product as well as product recalls, the inventory requirements of each licensee, the impact of competitive products, the timing and scope of Estalis® and Estradot launches and commercialization efforts by Novartis Pharma, CombiPatch® prescription trends in the United States, the impact of the HT studies on prescriptions for our hormone replacement products, the product pricing of each licensee, the timing of certain royalty reconciliations and payments under our license agreements, the timing of FDA approval, including our methylphenidate patch or our fentanyl patch,

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if any, and any subsequent product launch of new products, and the success of Endo s and Shire s commercialization efforts. Our earnings may fluctuate because of, among other things, fluctuations in research and development spending resulting from the timing of clinical trials involving products in development. Novartis is entitled to an annual $6.1 million preferred return, which has the effect of reducing our share of Novogyne s income in the first quarter of each year.

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

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

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

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

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

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

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

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

Our ability and our marketing partners ability to commercialize our products, including our methylphenidate patch, is dependent in part on obtaining reimbursement from government health authorities, private health insurers and managed care organizations. The trend toward managed healthcare in the United States and the prominence of health maintenance organizations (HMOs) and similar entities could significantly influence the purchase of our products, resulting in lower prices and lower demand. This is particularly true in a market that includes generic alternatives, such as the ADHD market. There can be no assurance that Shire will obtain acceptable reimbursement status for our methylphenidate patch. Additionally, if Strattera®, a non-stimulant ADHD treatment, becomes recognized as therapeutically superior to stimulant-based treatments such as our methylphenidate patch, the reimbursement status of our methylphenidate patch may be adversely affected. There can also be no assurance that managed care agreements established by Novartis will not adversely affect Novogyne s financial results.

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

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

We may be exposed to product liability claims and there can be no assurance of adequate insurance.

Like all pharmaceutical companies, the testing, manufacturing and marketing of our products may expose us to potential product liability and other claims resulting from their use. Noven has been named as a defendant in one case in which a plaintiff alleges personal injury from the use of HT products, including CombiPatch®, which is manufactured by Noven and distributed by Novogyne. In

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addition, Novartis has advised Noven that Novartis has been named as a defendant in at least 11 additional lawsuits involving approximately 22 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven products, Vivelle®, Vivelle-Dot™ and CombiPatch®. If any such claims against us are successful, we may be required to make significant compensation payments and suffer the associated adverse publicity. Even unsuccessful claims could result in the expenditure of funds in litigation and the diversion of management time and resources. We maintain product liability insurance, but there can be no assurance that our insurance will cover all future claims or that we will be able to maintain existing coverage or obtain additional coverage at reasonable rates. Our 2005 product liability insurance policy is more expensive with significantly less coverage and higher deductibles than in previous years. If a claim is not covered or if our coverage is insufficient, we may incur significant liability payments that would negatively affect our business, financial position or results of operations.

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

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

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

We rely on insurance to protect us from many business risks, including product liability, business interruption, property and casualty loss, employment practices liability and directors and officers liability. The cost of insurance has risen significantly in the past year. In response, we may increase deductibles and/or decrease certain coverages to mitigate these costs. There can be no assurance that the insurance that we maintain and intend to maintain will be adequate, or that the cost of insurance and limitations in coverage will not adversely affect our business, financial position or results of operations. Furthermore, if is possible that, in some cases, coverage may not be available at any price.

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

In the normal course of business, we enter into license, supply, employment and other agreements that include indemnification provisions. The Novogyne joint venture operating

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agreement contains an indemnification provision as do certain supply and license agreements between and among Noven, Novartis and Novogyne. The various indemnification provisions in these agreements are not uniform and, depending on the circumstances, may be subject to differing legal interpretations. As a consequence, it may be difficult in certain circumstances for us to determine or predict in advance what indemnification obligations Noven may owe to Novogyne or Novartis under these provisions or, alternatively, what obligations may be owed to Noven by these parties, including as it relates to potential damages, settlement amounts and defense costs associated with the product liability lawsuits that claim the use of products manufactured by Noven and distributed by Novogyne. While insurance coverage may mitigate the costs of some of our obligations under these indemnification provisions, our business, financial position and results of operations could be harmed if we are required to perform under these indemnification provisions and there is no or insufficient insurance coverage.

Our success depends on attracting and retaining our key employees.

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

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

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

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

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The operating agreement for our joint venture with Novartis has a buy/sell provision that either party may trigger by notifying the other party of the price at which the triggering party would be willing to acquire the joint venture. As a result of the buy/sell provision, any potential acquirer of Noven faces the possibility that Novartis could trigger this provision at any time and thereby require the acquirer to either purchase for cash Novartis interest in Novogyne (which would include the net present value of Novartis $6.1 million annual preferred return) or to sell its interest in Novogyne to Novartis. The existence of the buy/sell provision and the uncertainty it may create could discourage an acquisition of Noven by a third party, which could have an adverse effect on the market price for our common stock. Finally, the operating agreement gives Novartis the right to dissolve the joint venture in the event of a change in control of Noven if the acquirer is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot subject to the terms of Novartis prior arrangement with us, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement. This dissolution provision could have an anti-takeover effect with respect to a top ten pharmaceutical company.

The market price for our common stock is volatile.

The market price of our common stock is volatile. Since January 1, 2004, our common stock traded as low as $14.62 per share and as high as $25.96 per share. Any number of factors, including some over which we have no control and some unrelated to our business or financial results, may have a significant impact on the market price of our common stock, including: announcements by us or our competitors of technological innovations or new commercial products, changes in governmental regulation, receipt by us or one of our competitors of regulatory approvals or adverse regulatory determinations, developments relating to our patents or proprietary rights of one of our competitors, publicity regarding actual or potential medical results or risks for products that we or one of our competitors market or has under development; and period-to-period changes in financial results and the economy generally. We, like any other company with a volatile stock price, may be subject to further securities litigation, which could have a material adverse effect on our business and financial results.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements at page 79 of this report.

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

Not applicable.

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Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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

Management s Report on Internal Controls over Financial Reporting

Noven s management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, a company s principal executive and principal financial officers and effected by a company s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements whether arising from fraud or simple error. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate over time because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Noven s management assessed the effectiveness of the company s internal control over financial reporting as of December 31, 2004. In making this assessment, Noven s management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework.

Based on our assessment, Noven s management believes that, as of December 31, 2004, Noven s internal control over financial reporting is effective based on those criteria.

Deloitte & Touche LLP, Noven s independent registered public accounting firm, have issued an audit report on Noven s management s assessment of the company s internal control over financial reporting. This report appears on page 68.

Other Matters

We do not control Novogyne and Novartis performs all of Novogyne s financial, accounting, inventory, sales and sales deductions functions. The assessment of our management and the report of our independent registered public accounting firm thereon did not include the internal controls of our equity investment in Novogyne and the foregoing information should be considered in that light. In the course of its audit of Novogyne s financial statements included in this Annual Report on Form 10-K, Novogyne s independent registered public accounting firm identified what it believes is a significant deficiency in Novogyne s internal controls which related to oversights by Novartis in connection with Novogyne s accounting for certain rebate accruals. These oversights resulted in an immaterial adjustment at Novogyne in the fourth quarter of 2004. We have been advised that the Audit and Compliance Committee of Novartis AG has engaged outside counsel and is conducting an ongoing internal investigation of this matter. It is not possible for us to predict what impact, if any, Novartis internal investigation may have. To our knowledge, none of the issues that are the subject of the investigation involves Noven, Noven s accounting policies or practices, or any of Noven s officers, directors or employees.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited management s assessment, included in the accompanying Management s Report on Internal Controls over Financial Reporting, that Noven Pharmaceuticals, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of

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Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended December 31, 2004 of the Company and our report dated March 15, 2005 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants

Miami, Florida
March 15, 2005

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Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The information concerning directors required by item 10 is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders. The information concerning executive officers required by item 10 is contained in the discussion entitled Executive Officers of the Registrant in Part I hereof.

Item 11. Executive Compensation.

The information required by item 11 is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders.

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

(a) Equity Plan Compensation Information

The following table provides summary information concerning the equity awards under Noven s compensation plans (option and share amounts in thousands) as of December 31, 2004:

Plan Category	Number of Securities To Be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding Securities Reflected in First Column)
Equity Compensation Plans Approved by Security Holders	3,739	$ 17.69	882
Equity Compensation Plans Not Approved by Security Holders	23	$ 12.58	

Total	3,762	$	17.66	882

(b) Information Concerning Security Ownership

The information is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders.

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Item 13. Certain Relationships and Related Transactions.

The information required by item 13 is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders.

Item 14. Principal Accounting Fees and Services.

The information required by item 14 is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See Index to Financial Statements at page 79 of this report.

(a)(2) Financial Statement Schedules

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

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(a)(3) Exhibits

Exhibit Number	Description	Method of Filing
3.1	Noven s Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 of Noven s Form 10-K for the year ended December 31, 1998 (File No. 0-17254).
3.2	Noven s Certificate of Amendment of Certificate of Incorporation dated June 5, 2001.	Incorporated by reference to Exhibit 3.1 of Noven s Form 10-Q for the quarter ended June 30, 2001 (File No. 0-17254).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of Noven Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.3 of Noven s Form 10-K for the year ended December 31, 2001 (File No. 0-17254).
3.4	Noven s Bylaws, as amended and restated as of February 8, 2001.	Incorporated by reference to Exhibit 3.2 of Noven s Form 10-K for the year ended December 31, 2000 (File No. 0-17254).
4.1	Rights Agreement by and between Noven and American Stock Transfer & Trust Company dated November 6, 2001.	Incorporated by reference to Exhibit 4.1 of Noven s Form 8-K dated November 6, 2001 (File No. 0-17254).
10.1	Noven Pharmaceuticals, Inc. Amended and Restated Stock Option Plan.*	Incorporated by reference to Noven s Form 10-K for the year ended December 31, 1990 (File No. 0-17254), as further amended on June 23, 1992 and incorporated by reference to the definitive Proxy Statement dated May 11, 1992, for the Annual Meeting of Shareholders held on June 23, 1992.
10.2	Amendment to Noven Pharmaceuticals, Inc. Amended and Restated Stock Option Plan.*	Incorporated by reference to Noven s Form 10-Q for the quarter ended June 30, 1999 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.3	Noven Pharmaceuticals, Inc. 1997 Stock Option Plan.*	Incorporated by reference to Noven s definitive Proxy Statement dated May 1, 1997, for the Annual Meeting of Shareholders held on June 3, 1997.
10.4	Amendment to Noven Pharmaceuticals, Inc. 1997 Stock Option Plan.*	Incorporated by reference to Noven s Form 10-Q for the quarter ended June 30, 1999 (File No. 0-17254).
10.5	Noven Pharmaceuticals, Inc. 1999 Long-Term Incentive Plan.*	Incorporated by reference to Noven s definitive Proxy Statement dated April 12, 2004, for the Annual Meeting of Shareholders held on May 18, 2004.
10.6	Amended and Restated Employment Agreement between Noven and Robert C. Strauss dated as of November 5, 2003.*	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 2003 (File No. 0-17254).
10.7	Form of Employment Agreement (Change in Control), between Noven and each of Eduardo G. Abrao, Diane M. Barrett, Jeffrey F. Eisenberg, W. Neil Jones and Juan A. Mantelle.*	Incorporated by reference to the Form of Employment Agreement (Change in Control) filed as Exhibit 10.4 of Noven s Form 10-Q for the quarter ended September 30, 2004 (File No. 0-17254).
10.8	Form of Indemnification Agreement for Directors and Officers.	Incorporated by reference to Exhibit 10.4 of Noven s Form 10-K for the year ended December 31, 1998 (File No. 0-17254).
10.9	License Agreement between Noven and Ciba-Geigy Corporation dated November 15, 1991 (with certain provisions omitted pursuant to Rule 406).	Incorporated by reference to Exhibit 10.9 of Amendment No. 1 to Noven s Registration Statement on Form S-2 (File No. 33-45784).
10.10	Industrial Lease between Rhône-Poulenc Rorer Pharmaceuticals Inc. and Noven dated March 23, 1993 and effective February 16, 1993 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.20 of Noven s Form 10-K for the year ended December 31, 1993 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.11	Operating Agreement of Vivelle Ventures LLC (a Delaware limited liability company) dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.33 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.12	Amendment to Operating Agreement between Novartis Pharmaceuticals Corporation and Noven dated March 29, 2001.	Incorporated by reference to Exhibit 10.7 to Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.13	Marketing and Promotional Services Agreement by and between Noven and Vivelle Ventures LLC dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.4 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.14	First Amendment to Marketing and Promotional Services Agreement between Vivelle Ventures LLC and Noven dated March 29, 2001.	Incorporated by reference to Exhibit 10.6 to Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.15	Sublicense Agreement by and among Novartis Pharmaceuticals Corporation, Noven and Vivelle Ventures LLC dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.35 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.16	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer, Inc. dated September 30, 1999 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended September 30, 1999 (File No. 0-17254).
10.17	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer, Inc. dated September 30, 1999 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 1999 (File No. 0-17254).
10.18	Amendment No. 2 to Amended and Restated License Agreement between Rorer Pharmaceutical Products, Inc. and Noven Pharmaceuticals, Inc. dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.19	License Agreement between Noven and Novartis Pharma AG dated as of November 3, 2000 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 2000 (File No. 0-17254).

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

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Exhibit Number	Description	Method of Filing
10.28	Agreement between Shire US Inc. and Noven, dated November 5, 2003.**	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended September 30, 2003 (File No. 0-17254).
10.29	Agreement between Noven and P&G Pharmaceuticals, Inc. dated April 28, 2003 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.29 of Noven s Form 10-K for the year ended September 30, 2003 (File No. 0-17254).
10.30	License Agreement between Noven and Endo Pharmaceuticals Inc. dated February 25, 2004 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.30 of Noven s Form 10-K for the year ended December 31, 2003 (File No. 0-17254).
10.31	Supply Agreement between Noven and Endo Pharmaceuticals Inc. dated February 25, 2004 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.31 of Noven s Form 10-K for the year ended December 31, 2003 (File No. 0-17254).
10.32	Form of Incentive Stock Option Agreement.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended September 30, 2004 (File No. 0-17254).
10.33	Form of Non-Qualified Stock Option Agreement.*	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 2004 (File No. 0-17254).
10.34	Form of Non-Qualified Stock Option Agreement (Non-Employee Director).*	Incorporated by reference to Exhibit 10.3 of Noven s Form 10-Q for the quarter ended September 30, 2004 (File No. 0-17254).
10.35	Agreement between Shire US Inc. and Noven, dated June 15, 2004 (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 June 30, 2004 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.36	Letter Agreement between Noven and Proctor & Gamble Pharmaceuticals, Inc., dated December 22, 2004 (with certain provisions omitted pursuant to Rule 24b-2).	Filed herewith
10.37	Industrial Long-Term Lease, dated February 22, 2005, between Noven and Deerwood Commerce Center LLC.**	Filed herewith.
11	Computation of Earnings per Share.	Filed herewith.
21	Subsidiaries of the Registrant.	Filed herewith.
23.1	Consent of Deloitte & Touche LLP.	Filed herewith.
23.2	Consent of PricewaterhouseCoopers LLP.	Filed herewith.
31.1	Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to Securities Exchange Act Rules 13a-15(c) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to Securities Exchange Act Rules 13a-15(c) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32.1	Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32.2	Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

* Compensation Plan or Agreement.

**

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

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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 16, 2005 NOVEN PHARMACEUTICALS, INC.

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

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

Signature	Title	Date
By: /s/Robert C. Strauss Robert C. Strauss (President, CEO & Chairman of the Board)	Principal Executive Officer and Chairman of the Board	March 16, 2005
By: /s/Diane M. Barrett Diane M. Barrett (Vice President & Chief Financial Officer)	Principal Financial and Accounting Officer	March 16, 2005
By: /s/Sidney Braginsky Sidney Braginsky	Director	March 16, 2005
By: /s/John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 16, 2005
By: /s/Donald A. Denkhaus Donald A. Denkhaus	Director	March 16, 2005
By: /s/Pedro P. Granadillo Pedro P. Granadillo	Director	March 16, 2005
By: /s/Robert G. Savage	Director	March 16, 2005

	Robert G. Savage		
By:	/s/Wayne P. Yetter	Director	March 16, 2005
	Wayne P. Yetter		

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INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2004 and 2003, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004. 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, 2004, 2003, and 2002. Noven s equity in Vivelle Ventures LLC of $26,233,000 and $28,368,000 at December 31, 2004 and 2003, respectively, and Noven s share of that joint venture s income of $17,641,000, $17,094,000, and $14,368,000 for the years ended December 31, 2004, 2003, 2002, respectively, are included in the accompanying financial statements. Such financial statements of Vivelle Ventures LLC were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such joint venture for 2004, 2003, and 2002, is based solely on the report of such other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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 report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of the other auditors, such financial statements present fairly, in all material respects, the financial position of Noven Pharmaceuticals, Inc. as of December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2005 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants

Miami, Florida
March 15, 2005

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NOVEN PHARMACEUTICALS, INC.

Balance Sheets
December 31, 2004 and 2003
(in thousands, except share data)

	2004	2003
Assets		
Current Assets:		
Cash and cash equivalents	$ 93,958	$ 83,381
Accounts receivable - trade (less allowance for doubtful accounts of $64 in 2004 and $84 in 2003)	5,395	3,809
Accounts receivable - Novogyne, net	10,098	6,320
Inventories	15,988	5,200
Net deferred income tax asset, current portion	6,700	8,000
Prepaid income taxes	9,344	2,154
Prepaid and other current assets	1,238	1,065
	142,721	109,929
Property, plant and equipment, net	22,587	18,354
Other Assets:		
Investment in Novogyne	26,233	28,368
Net deferred income tax asset	8,239	12,175
Patent development costs, net	2,174	1,977
Deposits and other assets	21	181
	36,667	42,701
	$ 201,975	$ 170,984
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 12,176	$ 3,970
Capital lease obligation - current portion	114	
Accrued liability - Shire	10,587	90
Accrued compensation and related liabilities	5,762	3,734
Other accrued liabilities	3,015	3,590
Deferred contract revenues	2,076	772
Deferred license revenues - current portion	11,642	21,112
	45,372	33,268
Long-Term Liabilities:		
Capital lease obligation	121	
Deferred license revenues	27,443	28,893

	72,936	62,161
Commitments and Contingencies (Note 7 and 14)		
Stockholders Equity:		
Preferred stock - authorized 100,000 shares of $.01 par value; no shares issued or outstanding		
Common stock - authorized 80,000,000 shares, par value $.0001 per share; issued and outstanding 23,481,264 in 2004 and 22,722,060 in 2003	2	2
Additional paid-in capital	88,236	79,244
Retained earnings	40,801	29,577
	129,039	108,823
	$ 201,975	$ 170,984

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Operations
Years Ended December 31, 2004, 2003 and 2002
(in thousands, except per share amounts)

	2004	2003	2002
Revenues:			
Product revenues - Novogyne:			
Product sales	$ 18,798	$ 15,932	$ 25,394
Royalties	5,204	4,978	4,505
Product revenues - Novogyne	24,002	20,910	29,899
Product revenues - third parties	12,869	16,206	20,300
Total product revenues	36,871	37,116	50,199
Contract and license revenues:			
Contract	5,021	2,024	1,787
License	3,999	4,026	3,386
Contract and license revenues	9,020	6,050	5,173
Net revenues	45,891	43,166	55,372
Expenses:			
Cost of products sold	20,101	19,482	22,973
Research and development	9,911	8,082	11,634
Marketing, general and administrative	17,271	15,858	14,257
Total expenses	47,283	43,422	48,864
(Loss) income from operations	(1,392)	(256)	6,508
Equity in earnings of Novogyne	17,641	17,094	14,368
Interest income, net	999	659	822
Income before income taxes	17,248	17,497	21,698
Provision for income taxes	6,024	6,301	7,819

Net income	$ 11,224	$ 11,196	$ 13,879
Basic earnings per share	$ 0.48	$ 0.50	$ 0.62
Diluted earnings per share	$ 0.46	$ 0.49	$ 0.60
Weighted average number of common shares outstanding:			
Basic	23,332	22,544	22,532
Diluted	24,305	22,989	23,321

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Stockholders Equity
Years Ended December 31, 2004, 2003 and 2002
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Total
Balance at December 31, 2001	22,482	$ 2	$ 77,394	$ 4,502	$ 81,898
Issuance of shares pursuant to stock option plan, net	97		771		771
Tax benefit from exercise of stock options			153		153
Issuance of options to charitable organization			40		40
Net income				13,879	13,879
Balance at December 31, 2002	22,579	2	78,358	18,381	96,741
Issuance of shares pursuant to stock option plan, net	245		1,617		1,617
Issuance of stock to outside directors	3		31		31
Tax benefit from exercise of stock options			527		527
Purchase and retirement of common stock	(105)		(1,289)		(1,289)
Net income				11,196	11,196
Balance at December 31, 2003	22,722	2	79,244	29,577	108,823
Issuance of shares pursuant to stock option plan, net	757		5,924		5,924
Issuance of stock to outside directors	2		34		34
Tax benefit from exercise of stock options			3,034		3,034
Net income				11,224	11,224
Balance at December 31, 2004	23,481	$ 2	$ 88,236	$ 40,801	$ 129,039

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Cash Flows
Years Ended December 31, 2004, 2003 and 2002
(in thousands)

	2004	2003	2002
Cash flows from operating activities:			
Net income	$ 11,224	$ 11,196	$ 13,879
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	2,285	2,278	2,216
Loss on disposal of equipment	347		
Amortization of patent costs	389	341	312
Amortization of non-competition agreement	167	400	400
Income tax benefits on exercise of stock options	3,034	527	153
Deferred income tax (benefit) expense	5,236	(6,944)	2,586
Expense related to issuance of shares of stock to outside directors and options to charitable organization	34	31	40
Recognition of deferred license revenues	(3,999)	(4,026)	(3,386)
Equity in earnings of Novogyne	(17,641)	(17,094)	(14,368)
Distributions from Novogyne	18,083	21,739	11,727
Changes in operating assets and liabilities:			
(Increase) decrease in accounts receivable - trade, net	(1,586)	550	(3,051)
(Increase) decrease in accounts receivable - Novogyne, net	(3,778)	(3,739)	2,577
(Increase) decrease in inventories	(10,788)	413	(1,289)
Increase in prepaid income taxes	(5,497)	(483)	
Increase in prepaid and other current assets	(173)	(524)	(237)
(Increase) decrease in deposits and other assets	(7)		26
Increase (decrease) in accounts payable	8,206	(1,092)	(558)
Increase in accrued liability - Shire	10,497	90	
Increase in accrued compensation and related liabilities	2,028	185	2,031
(Decrease) increase in other accrued liabilities	(575)	727	(756)
Increase (decrease) in deferred contract revenue	1,304	(57)	(588)
Increase in deferred license revenue	6,500	25,000	73
Direct expenses incurred in pursuit of Methylphenidate patch regulatory approval	(13,421)	(414)	
Cash flows provided by operating activities	11,869	29,104	11,787
Cash flows from investing activities:			
Purchases of property, plant and equipment, net	(6,529)	(4,400)	(2,749)
Payments for patent development costs, net	(586)	(322)	(262)
Cash flows used in investing activities	(7,115)	(4,722)	(3,011)
Cash flows from financing activities:			
Issuance of common stock from exercise of stock options	5,924	1,617	771
Purchase and retirement of common stock		(1,289)	

Repayments of capital leases	(101)	(13)	(252)
Cash flows provided by financing activities	5,823	315	519
Net increase in cash and cash equivalents	10,577	24,697	9,295
Cash and cash equivalents, beginning of year	83,381	58,684	49,389
Cash and cash equivalents, end of year	$ 93,958	$ 83,381	$ 58,684

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS:

Noven Pharmaceuticals, Inc. (Noven) was incorporated in Delaware in 1987 and is engaged in the research, development, manufacture and marketing of advanced transdermal drug delivery technologies and prescription transdermal products.

Noven and Novartis Pharmaceuticals Corporation (Novartis) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) (Novogyne), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. These products include Noven s transdermal hormone therapy patches marketed under the brand names Vivelle®, Vivelle-Dot and CombiPatch®. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne to third party customers.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

USE OF ESTIMATES:

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

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

CASH AND CASH EQUIVALENTS:

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

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INVENTORIES:

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

	2004	2003
Finished goods	$ 610	$ 806
Work in process	6,522	1,722
Raw materials	8,856	2,672
Total	$ 15,988	$ 5,200

Included in the amounts above as of December 31, 2004 were approximately $10.8 million in inventories to manufacture launch supplies of Noven s generic fentanyl patch for which an Abbreviated New Drug Application has been filed and is pending before the Food and Drug Administration (FDA). See Note 5 - Contract and License Agreements - Endo Collaboration and Note 14 - Fentanyl Inventories. The remaining inventories at December 31, 2004 and all of the inventories at December 31, 2003 relate to Noven s marketed products. As appropriate, provisions are made to reduce inventories to net realizable value. To date, Noven has not experienced any difficulty acquiring materials necessary to manufacture its products. Given that certain materials and compounds, including essential polymers used by Noven, are available from limited sources and, in some cases, a single supplier, no assurance can be given that Noven will not experience difficulty in the future. Other than products produced for commercial sale, Noven s policy is to immediately recognize as expense all inventory purchased for research and development purposes.

PROPERTY, PLANT AND EQUIPMENT:

Property, plant and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets ranging up to 40 years. Leasehold improvements are amortized over the life of the lease or the service life of the improvements, whichever is shorter. Major renewals and betterments are capitalized, while maintenance repairs and minor renewals are expensed as incurred.

SOFTWARE AND DEVELOPMENT COSTS:

Noven capitalizes purchased software which is ready for service and development costs for marketable software incurred from the time the preliminary project stage is completed until the software is ready for use. Under the provisions of SOP 98-1, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use , Noven capitalizes costs associated with software developed or obtained for internal use when the preliminary project stage is completed. Capitalized costs include only: (i) external direct costs of materials and services consumed in developing or obtaining internal-use software, and (ii) payroll and payroll-related costs for employees who are directly associated with and who devote time to the internal-use software project. Capitalization of such costs ceases no later than the point at which the project is substantially complete and ready for its intended purpose. For the years ended December 31, 2004 and 2003, approximately $0.9 million and $0.2 million, respectively, of these costs were capitalized.

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

IMPAIRMENT OF LONG LIVED ASSETS:

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

PATENT DEVELOPMENT COSTS:

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

INCOME TAXES:

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

COMMITMENTS AND CONTINGENCIES:

Noven accounts for commitments and contingencies in accordance with the provisions of SFAS No. 5, Accounting for Contingencies . SFAS 5 provides that accruals are to be established for contingencies that are probable and estimable. However, the estimation of the amount to accrue usually requires significant judgment. The establishment of allowances for returns related to product recalls requires Noven to make assumptions about future expected returns, actual returns, distribution and expiration dates of the affected product and overall trade inventory levels. Litigation accruals for estimated legal fees and settlement costs require Noven to make assumptions about the future outcome of each case based on current information and expected legal fees and expected insurance recovery, if any, that will be incurred. Accruals for pending IRS matters require Noven to make assumptions on estimated liabilities related to those matters (see Note 14).

REVENUE RECOGNITION:

Substantially all of Noven s product revenues were for sales to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis Pharma) and Aventis Pharma AG (Aventis) (see Notes 5 and 6). Revenues from product sales are recognized at the time of shipment when both title and the risks and rewards of ownership have been transferred to the buyer. Certain of Noven s license agreements provide that the ultimate supply price is based on a percentage of the licensee s net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price Noven is entitled to receive on sales to the licensee.

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Noven receives the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. Noven records any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, Noven records the adjustments on a cash basis. These amounts are included in product revenues.

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

Noven enters into certain contracts that have various terms and conditions that may have multiple revenue characteristics, including license revenues, contract revenues, product sales and manufacturing revenues. As prescribed by EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables , Noven analyzes each contract in order to separate each deliverable into separate units of accounting and then recognize revenues for those separated units at their fair value as earned in accordance with SEC Staff Accounting Bulletin Topic 13, Revenue Recognition (Topic 13). If each deliverable does not qualify as a separate unit of accounting, the deliverables are combined and the amounts under the contract are allocated to the combined deliverables. The appropriate recognition of revenue is then determined for the combined deliverables as a single unit of accounting.

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

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

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

additional payments upon completion of additional phases; and

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

For non-refundable up-front payments received prior to commencing work, Noven recognizes revenue based on the proportionate share of the work performed by Noven in any given period based on the total hours it expects to incur on the project to deliver all its obligations under the contract. Additional payments upon completion of additional phases and milestone payments are recorded when the specified performance criteria are achieved, as determined by the customer. The difference between the amount of the payments received and the amount recognized is recorded as deferred revenues until that amount is recognized. Each

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contract may have different payment terms. Therefore, the timing of revenue recognition may vary from contract to contract.

Revenues are net of an allowance for returns. Noven establishes allowances for returns for product that has been recalled or that it believes is probable of being recalled. The methodology used by Noven to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry. During 2003, Novartis initiated recalls of certain lots of CombiPatch® and Vivelle-Dot due to production issues. Revenues for 2003 are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively. Based on a review of available relevant information, including actual product returns and future expected returns, Noven and Novogyne reduced these allowances during 2004, which had the effect of increasing net revenues for 2004 by $0.6 million and $3.3 million for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase Noven s income before income taxes by $2.2 million for 2004. The effect on Novogyne of Novogyne s adjustment was to increase Novogyne s income before income taxes by $2.8 million for 2004. Therefore, if Noven s estimate concerning the amount of the product returns is incorrect or if Novartis should initiate further unexpected recalls, then Noven s results of operations could be materially different.

Noven s revenue recognition policy is in compliance with the requirements of Topic 13.

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 PER SHARE:

Noven computes its Earnings Per Share in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share . Basic earnings per share excludes all dilution. It is based on income attributable to common stockholders and the weighted average number of common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. Common stock equivalents are not included in the diluted earnings per share calculation if the effect of their inclusion would be antidilutive. The total number of common stock equivalents not included in the diluted earnings per share calculation as of December 31, 2004, 2003 and 2002 was 1,360,983, 2,107,959 and 2,238,306 shares, respectively, which represents out-of-the-money stock options.

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COMPREHENSIVE INCOME:

For the years ended December 31, 2004, 2003 and 2002, total comprehensive income was equal to net income.

EMPLOYEE STOCK PLANS:

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

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

	2004	2003	2002
Net income:			
As reported	$ 11,224	$ 11,196	$ 13,879
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(5,842)	(3,596)	(4,443)
Pro forma	$ 5,382	$ 7,600	$ 9,436
Basic earnings per share:			
As reported	$ 0.48	$ 0.50	$ 0.62
Pro forma	$ 0.23	$ 0.34	$ 0.42
Diluted earnings per share:			
As reported	$ 0.46	$ 0.49	$ 0.60
Pro forma	$ 0.22	$ 0.33	$ 0.40

SFAS 123 requires the use of option valuation models that require the input of highly subjective assumptions, including expected stock price volatility. Because Noven s stock options have characteristics significantly different from traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable measure of the fair value of its employee stock options.

The effect of applying the fair value method of accounting for stock options on reported net income and earnings per share for 2004, 2003 and 2002 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.

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The fair value of each option granted during 2004, 2003 and 2002 is estimated as $13.10, $7.01 and $9.65, respectively, on the date of the grant using the Black Scholes option-pricing model with the assumptions listed below:

	2004	2003	2002
Volatility	69.0%	80.0%	85.0%
Risk free interest rate	3.49%	3.22%	3.22%
Expected life (years)	5	5	6

As noted in the section Recent Accounting Pronouncements , in December 2004, the FASB issued Statement of Financial Accounting Standard 123(R) (SFAS 123(R)) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. Noven will be required to commence stock option expensing under SFAS 123(R) beginning July 1, 2005. Noven anticipates applying this statement for its third quarter beginning July 1, 2005, which would result in compensation expenses of approximately $3.9 million (not including tax effects) for the second half of 2005, based on option grants outstanding at December 31, 2004. The foregoing amount does not include compensation expense for any stock options that may be granted after January 1, 2005.

SEGMENT INFORMATION:

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

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 term nature of these items.

CONCENTRATIONS OF CREDIT RISK:

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

RECLASSIFICATION:

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

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RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46R, Consolidation of Variable Interest Entities (FIN 46). This Interpretation of Accounting Research Bulletin 51, Consolidated Financial Statements , addresses consolidation by business enterprises of variable interest entities which have one or both of the following characteristics: (i) the equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. Noven has applied this statement for its calendar year beginning January 1, 2004. Noven s investment in Novogyne is not considered a variable interest in a Variable Interest Entity (VIE) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to Noven, and the adoption of this interpretation has had no impact on Noven s financial statements. These conclusions are based on currently available information and require Noven to assess its investment interest and ownership rights in Novogyne. If Noven s conclusions or its underlying assumptions of factual information concerning its investment in Novogyne were to change, Novogyne may be considered a VIE and Noven s investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. Noven believes that even if a determination were made that Novogyne was a VIE at December 31, 2004, Novartis is the primary beneficiary due to its preferred return and its 51% equity interest in Novogyne and would continue to consolidate Novogyne.

In November 2004, the FASB issued Statement of Financial Accounting Standard No. 151 Inventory Costs - an amendment of ARB No. 43 Chapter 4 (SFAS 151), to clarify the accounting for abnormal amounts of idle facility expense, freight or wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the so abnormal criterion outlined in Accounting Research Bulletin 43, Chapter 4, Inventory Pricing . SFAS 151 also introduces the concept of normal capacity and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Noven is currently assessing SFAS 151 and Noven is unable to estimate the impact it will have on its results of operations and financial condition.

In December 2004, the FASB issued SFAS No. 123(R) Share-Based Payment (Revised 2004) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award, which is generally over the vesting period. SFAS 123(R) replaces SFAS 123, Accounting for Stock-Based Compensation , and supersedes APB 25, Accounting for Stock Issued to Employees . For public companies such as Noven, the statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. Noven anticipates applying this statement for its third quarter beginning July 1, 2005, which would result in compensation expenses of approximately $3.9 million for the second half of 2005, based on option grants outstanding at December 31, 2004. The foregoing amount does not include compensation expense for any stock options that may be granted after January 1, 2005.

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See Employee Stock Plans for a discussion on fair value option valuation models and assumptions used in making this estimate.

3. CASH FLOW INFORMATION:

Cash payments for income taxes were $5.4 million, $13.2 million and $6.1 million in 2004, 2003 and 2002, respectively. Cash payments for interest were $18,000, $1,000 and $14,000 in 2004, 2003 and 2002, respectively.

Non-cash Operating Activities

In connection with the CombiPatch® transaction described in Note 5 below, in March 2001, Noven recorded a $40.0 million receivable from Novogyne and a $40.0 million payable to Aventis Pharmaceuticals, the United States pharmaceuticals business of Aventis. In 2002 Novogyne paid $10.0 million directly to Aventis.

In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state tax payments on behalf of its owners, Noven and Novartis. Novogyne paid $1.7 million in each of April 2004 and 2003 to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state tax payment. This payment was deemed a distribution to Noven.

Noven recorded a $3.0 million, $0.5 million and $0.2 million income tax benefit to additional paid-in capital derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options in 2004, 2003 and 2002, respectively.

Non-cash Investing Activities

In 2004 Noven entered into capital lease obligations totaling $0.3 million for new equipment.

4. PROPERTY, PLANT AND EQUIPMENT, NET:

Property, plant and equipment consists of the following at December 31, 2004 and 2003 (in thousands, except estimated useful lives):

	2004	2003	Estimated Useful Lives (in years)
Land	$ 2,540	$ 2,540	
Building and improvements	3,166	3,107	40
Leased property and leasehold improvements	12,655	9,926	15-31
Manufacturing and other equipment	15,193	12,844	3-10
Furniture	1,439	1,210	9-10
Software and software development costs	3,028	2,115	3
	38,021	31,742	
Less accumulated depreciation and amortization	(15,434)	(13,388)	
	$ 22,587	$ 18,354	

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5. CONTRACT AND LICENSE AGREEMENTS:
HORMONE THERAPY COLLABORATIONS:

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

Aventis License

Noven has two license agreements with Aventis. These agreements grant Aventis the right to market Noven s first generation transdermal estrogen delivery system worldwide except for the United States and Canada and to market Noven s transdermal combination estrogen/progestin delivery system worldwide. The agreements also grant Aventis the right to market Noven s second generation transdermal estrogen delivery system in Japan. In June 1992, as part of the license agreements, Aventis funded $7.0 million for the construction of a manufacturing facility for the production by Noven of transdermal drug delivery systems. Noven leases the facilities from Aventis for $1.00 per year for a term that expires upon the earlier of 2024 or the termination of Noven s license agreement with Aventis. Noven has the right to purchase the facility at any time for Aventis book value ($1.6 million as of December 31, 2004), or when fully depreciated, for $1.00. Aventis may terminate the lease prior to the expiration of its term upon termination or expiration of Noven s 1992 license agreement with Aventis. For accounting purposes, Noven treated the exchange of the funding of the facility for the license as a non-monetary exchange at fair value. Noven has determined that the fair market value of the license was $7.0 million, based on the amount Aventis paid for the construction of the manufacturing facility. Noven recorded both the facility and deferred license revenues at amounts equal to the funds advanced by Aventis, which are deferred and recognized as depreciation expense and license revenues over the life of the underlying lease, which expires in 2024. At December 31, 2004 and 2003, the carrying amount of the leased property and deferred revenues was $4.3 million and $4.5 million, respectively.

Novartis Pharma Sublicenses from Aventis

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

Novartis Pharma License of Estradot

In November 2000, Noven entered into an exclusive license agreement with Novartis Pharma pursuant to which Noven granted Novartis Pharma the right to market Noven s second generation transdermal estrogen delivery system under the name Estradot in all countries other

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than the United States, Canada and Japan. The agreement also grants Novartis Pharma marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by Noven. Noven received an up-front license payment of $20.0 million upon execution of the agreement. The up-front payment was deferred and is being recognized as license revenues over 10 years beginning in the fourth quarter of 2000. Noven subsequently received a $5.0 million milestone payment in the fourth quarter of 2001 that is being recognized as license revenues beginning in the first quarter of 2002 through the fourth quarter of 2010.

Novogyne Marketing Rights of CombiPatch®

Novogyne acquired the exclusive United States marketing rights to CombiPatch® in March 2001 in a series of transactions involving Novogyne, Noven, Novartis and Aventis. Prior to the transaction, Aventis had been Noven s exclusive licensee for CombiPatch® in the United States. The transaction was structured as (i) a direct purchase by Novogyne from Aventis of certain assets for $25.0 million, which was paid at closing, (ii) a grant-back by Aventis to Noven of certain intellectual property rights relating to CombiPatch®, and (iii) a simultaneous license by Noven to Novogyne of these intellectual property rights. The consideration payable by Noven to Aventis, and by Novogyne to Noven, was $40.0 million, which was due and paid in four quarterly installments of $10.0 million each, payable beginning June 1, 2001. Novogyne agreed to indemnify Noven against Noven s obligation to Aventis. In 2002 and 2001, Novogyne paid $10.0 million and $30.0 million, respectively, directly to Aventis. As a consequence of the transaction and under the terms of Noven s existing license agreement with Aventis, Noven received $3.5 million from Aventis, which amount was deferred and is being recognized as license revenues over ten years beginning in the first quarter of 2001.

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

ENDO COLLABORATION:

In July 2003, Noven submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch containing fentanyl, an opioid analgesic and a Schedule II controlled substance, and is indicated for the management of chronic pain. Noven s ANDA for this product was accepted for filing as of October 1, 2003 and is under review at the FDA. Johnson & Johnson s patent and exclusivity status for Duragesic® expired in January 2005, after which the FDA approved the fentanyl transdermal system ANDA filed by Mylan Laboratories. Also in January 2005, the FDA denied several citizen petitions intended to prevent or delay the approval of certain generic versions of Duragesic®.

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In February 2005, the FDA approved a Supplemental New Drug Application filed by Johnson & Johnson for new labeling for its Duragesic® product. Noven has been advised by the FDA that all pending ANDAs relating to the Duragesic® product, including Noven s ANDA, will be required to be amended prior to approval to reflect recent changes in the Duragesic® label. Noven is currently working with the FDA with respect to a revised label for its fentanyl patch. Once finalized, Noven will repackage existing inventory to reflect the revised labeling. Noven understands that there are other pending Duragesic® ANDAs, and we are unable to predict the timing or the impact of the required labeling changes on any pending ANDA, nor are we able to predict the timing of approval of any pending ANDA.

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

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

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

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

Of the $8.0 million received at signing, $6.5 million will be recognized as license revenues as earned over a 10-year period, which is the estimated product life cycle. The remaining $1.5 million is being recognized as contract revenues over the course of feasibility development of any additional patches developed under the Noven/Endo collaboration.

SHIRE COLLABORATION:

In the first quarter of 2003, Noven signed an agreement to license the exclusive global rights to market its methylphenidate patch to Shire for payments of up to $150.0 million and

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ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25.0 million was paid upon closing of the transaction in April 2003; (ii) $50.0 million is payable upon receipt of final marketing approval for the methylphenidate patch by the FDA; and (iii) three installments of $25.0 million each are payable upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual net sales of the methylphenidate patch, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, Noven entered into a long-term supply agreement under which it expects to manufacture and supply its methylphenidate patch to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, Noven s manufacturing revenues from sales of its methylphenidate patch would be adversely affected. Pursuant to the agreement, under certain circumstances Shire has the right to require Noven to repurchase the product rights for $5.0 million.

In April 2003, Noven received a not approvable letter from the FDA relating to its methylphenidate patch NDA. In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire are proceeding with the development of the methylphenidate patch. Development efforts include additional clinical studies, including another Phase 3 study. Pursuant to the agreements between the parties, Shire is managing these studies and Noven has committed to fund them. Noven s direct costs incurred in pursuit of approval are being deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven s research and development expenses in 2004 and are not expected to impact research and development expenses in 2005, although the direct expenses incurred in pursuit of FDA approval will reduce Noven s cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of December 31, 2004, the amount of deferred revenues was $5.7 million (which excludes the $5.0 million of deferred revenues related to the repurchase right described below) and Noven does not expect its prospective cost in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending NDA for Noven s methylphenidate patch during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for Noven s methylphenidate patch.

Under Noven s agreements with Shire, Shire has certain rights to terminate the license of Noven s methylphenidate patch, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable product. If Shire were to terminate on this basis, all product rights would revert to Noven, and Noven would retain the $25.0 million previously paid by Shire. Shire also has the right to require Noven to repurchase the product rights to the methylphenidate patch for $5.0 million under certain circumstances.

In June 2004, Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for Attention Deficit Hyperactivity Disorder. The agreement provides for the payment to Noven of up to $5.0 million if certain development milestones are

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achieved. The product is in pre-clinical development and Noven is recognizing payments received as contract revenue as the work is performed.

P&G PHARMACEUTICALS COLLABORATION:

In April 2003, Noven established a collaboration with Procter & Gamble Pharmaceuticals, Inc. (P&G Pharmaceuticals) for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa®, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&G Pharmaceuticals withdrew its NDA for Intrinsa ® in December 2004 based on feedback from an FDA Advisory Committee and has stated its intention to file a new NDA with additional clinical data. During 2004, Noven earned $4.4 million under the P&G Pharmaceuticals collaboration. Of the $4.4 million, $3.0 million was earned in the fourth quarter of 2004 and related to the attainment of a product development milestone as determined by P&G Pharmaceuticals.

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

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

The condensed Statements of Operations of Novogyne for the years ended December 31, 2004, 2003 and 2002 are as follows (in thousands):

	2004	2003	2002
Gross revenues	$ 124,791	$ 120,282	$ 130,235
Sales allowances	13,154	11,279	13,478
Sales returns allowances	6,224	7,926	14,272
Sales allowances and returns	19,378	19,205	27,750
Net revenues	105,413	101,077	102,485
Cost of sales	21,576	21,485	26,136
Selling, general and administrative expenses	35,624	30,673	33,091
Amortization of intangible assets	6,179	6,179	6,179
Income from operations	42,034	42,740	37,079
Interest income	191	182	350
Net income	$ 42,225	$ 42,922	$ 37,429
Noven s equity in earnings of Novogyne	$ 17,641	$ 17,094	$ 14,368

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The activity in the Investment in Novogyne account for the years ended December 31, 2004, 2003 and 2002 is as follows (in thousands):

	2004	2003	2002
Investment in Novogyne, beginning of year	$ 28,368	$ 34,684	$ 32,043
Equity in earnings of Novogyne	17,641	17,094	14,368
Cash distributions from Novogyne	(18,083)	(21,739)	(11,727)
Non-cash distribution from Novogyne	(1,693)	(1,671)	
Investment in Novogyne, end of year	$ 26,233	$ 28,368	$ 34,684

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%. The non-cash distribution from Novogyne represented a $1.7 million tax payment to the New Jersey Department of Revenue made by Novogyne on Noven s behalf in each of April 2004 and 2003. As discussed in Note 3, such payment was deemed a distribution from Novogyne to Noven.

The condensed Balance Sheets of Novogyne at December 31, 2004 and 2003 are as follows (in thousands):

	2004	2003
Current assets	$ 26,299	$ 24,977
Long-term assets	38,622	44,801
Total assets	64,921	69,778
Allowance for returns	9,169	14,240
Other liabilities	13,466	7,338
Total liabilities (all of which are current)	22,635	21,578
Members capital	$ 42,286	$ 48,200

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The activity for the allowance for returns for the three years ended December 31, 2004 is as follows (in thousands):

Balance December 31, 2001	$ 6,673
Expense related to expired product	14,272
Deductions	(8,165)
Balance December 31, 2002	12,780
Expense related to expired product	1,426
Expense related to product recalls	6,500
Deductions	(6,466)
Balance December 31, 2003	14,240
Expense related to expired product	9,569
Reductions in product recalls expense	(3,345)
Deductions	(11,295)
Balance December 31, 2004	$ 9,169

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

The joint venture operating agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If Noven is the purchaser, then Noven must pay an additional amount equal to the net present value of

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Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. Novartis is a larger company with greater financial resources, and therefore, may be in a better position to be the purchaser if the provision is triggered. In addition, this buy/sell provision may have an anti-takeover effect on Noven since a potential acquirer of Noven will face the possibility that Novartis could trigger this provision at any time and thereby require any acquirer to either purchase Novartis interest in Novogyne or to sell its interest in Novogyne to Novartis.

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

During the years ended December 31, 2004, 2003 and 2002, Noven had the following transactions with Novogyne (in thousands):

	2004	2003	2002
Revenues:			
Trade product	$ 15,216	$ 12,411	$ 21,984
Sample product and other	3,582	3,521	3,410
Royalties	5,204	4,978	4,505
	$ 24,002	$ 20,910	$ 29,899
Reimbursed expenses:			
Services	$ 20,014	$ 18,652	$ 18,345
Product specific marketing expenses	7,780	5,608	7,535
Reimbursed expenses	$ 27,794	$ 24,260	$ 25,880

As of December 31, 2004 and 2003, the Accounts Receivable Novogyne, net is as follows (in thousands):

	2004	2003
Sales of product	$ 893	$ 2,867
Services provided by Noven	8,594	4,255
Royalty	1,294	1,556
Allowance for product recall	(98)	(1,513)
Deferred profit on Novogyne inventory and other	(585)	(845)
	$ 10,098	$ 6,320

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7. OPERATING AND CAPITAL LEASES:

The Company has various operating and capital leases for computers and equipment. Lease expense under operating leases was approximately $0.5 million, $0.3 million and $0.3 million for the years ended December 31, 2004, 2003 and 2002, respectively.

The future minimum rental payments required under noncancelable operating and capital leases as of December 31, 2004 are as follows (in thousands):

	Operating Leases	Capital Leases
2005	$ 391	$ 125
2006	218	125
2007	116	
2008	17	
2009	14	
Thereafter		
Operating lease obligation	$ 756	250
Less: portion representing interest		(15)
Capital lease obligation		235
Less: Current portion		(114)
Capital lease obligation, net of current portion		$ 121

8. INCOME TAXES:

The provision (benefit) for income taxes in 2004, 2003 and 2002 consists of (in thousands):

	2004	2003	2002
Current income taxes:			
Federal	$ 638	$ 11,516	$ 4,430
State	150	1,729	803
	788	13,245	5,233
Deferred income tax (benefit) expense:			
Federal	4,322	(5,620)	2,518
State	914	(1,324)	68
	5,236	(6,944)	2,586
Income tax expense	$ 6,024	$ 6,301	$ 7,819

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

	2004	2003
Deferred income tax assets:		
Deferred license revenue	$ 10,992	$ 16,235
Joint venture interest	2,506	3,182
Inventory adjustments	1,845	369
Allowance for returns	132	789
Other	544	234
Total deferred income tax assets	16,019	20,809
Deferred income tax liabilities:		
Basis difference in fixed assets	(1,080)	(634)
Net deferred income tax asset	$ 14,939	$ 20,175

Realization of the net deferred income tax asset of $14.9 million and $20.2 million at December 31, 2004 and 2003, respectively, is dependent upon generating sufficient future taxable income. Although realization is not assured, management believes it is more likely than not that the net deferred income tax asset will be realized based upon estimated future income of Noven and, accordingly, no valuation allowance for the net deferred income tax asset was deemed necessary at December 31, 2004 and 2003.

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, 2004, 2003 and 2002, Noven credited $3.0 million, $0.5 million and $0.2 million, respectively, to additional paid-in capital related to the tax benefits from the exercise of stock options.

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

	2004		2003		2002	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$ 6,037	35.0	$ 6,124	35.0	$ 7,594	35.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	691	4.0	264	1.5	566	2.6
Extraterritorial income exclusion	(179)	(1.0)	(105)	(0.6)		
Research and development expenditures credit	(135)	(0.8)	(5)		(396)	(1.8)
(Reduction)/Increase in IRS audit accrual	(400)	(2.3)	700	4.0		
Change in effective deferred tax rate			(700)	(4.0)		
Other	10		23	0.1	55	0.2
Income tax expense	$ 6,024	34.9	$ 6,301	36.0	$ 7,819	36.0

9. STOCKHOLDERS EQUITY:

Noven established its 1999 Long-Term Incentive Plan (the 1999 Plan) on June 8, 1999. The 1999 Plan replaced Noven s 1997 Stock Option Plan (the 1997 Plan) and no future stock option awards may be granted under the 1997 Plan. The 1999 Plan as amended in May 2004 provides for the granting of incentive and non-qualified stock options, stock awards (including restricted stock), and other permitted awards to selected individuals for up to 4,768,848 shares, including 2,768,848 shares that remained available under the 1997 Plan at the time of its termination. At December 31, 2004, all awards granted under the 1999 Plan have been stock options with the exception of unrestricted stock awards for a total of 4,534 shares. The terms and conditions of stock options (including price, vesting schedule, term and number of shares) and other permitted awards under the 1999 Plan are determined by the Compensation and Stock Option Committee, which administers the 1999 Plan. The per share exercise price of (i) non-qualified stock options can not be less than the fair market value of the common stock on the date of grant, (ii) incentive stock options 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, 2004, there were 3,623,402 stock options issued and outstanding under the 1999 Plan. Generally, the options vest over a period of four or five years, beginning one year after date of grant, and expire seven years after date of grant.

The 1997 Plan, originally effective January 1, 1997, provided for the granting of up to 4,000,000 incentive and non-qualified stock options. At December 31, 2004, there were 115,821

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

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

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

	2004		2003		2002	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	3,919	$ 14.51	3,410	$ 15.20	2,845	$ 15.57
Granted	1,015	21.70	956	10.60	871	14.08
Exercised	(769)	8.03	(245)	6.60	(101)	8.02
Canceled and expired	(426)	15.52	(202)	17.17	(205)	19.14
Outstanding at end of year	3,739	17.69	3,919	14.51	3,410	15.20
Options exercisable at end of year	1,541	18.35	1,669	14.78	1,404	13.23
Shares of common stock reserved	4,644		4,414		4,722	

The following table summarizes information concerning outstanding and exercisable options at December 31, 2004 (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 - 6.16	102	1.2	$ 5.20	102	$ 5.20
7.86 - 11.64	918	5.2	10.35	327	10.14
12.12 - 17.88	1,240	4.3	14.24	571	14.12
18.45 - 23.00	980	7.0	22.08	135	19.79
31.31 - 41.81	499	2.8	33.68	406	33.77
	3,739			1,541	

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,

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

10. SHARE REPURCHASE PROGRAM:

In the first quarter of 2003, Noven s Board of Directors authorized a share repurchase program under which Noven may acquire up to $25 million of its common stock. As of December 31, 2003, Noven had repurchased 105,000 shares of its common stock at an aggregate price of approximately $1.3 million. These shares were retired on March 31, 2003. No shares were repurchased during 2004.

11. 401(k) SAVINGS PLAN:

On January 1, 1997, Noven established a savings plan under section 401(k) of the Internal Revenue Code (the 401(k) Plan) covering substantially all employees who have completed three months of service and have reached the age of twenty-one. This plan allows eligible participants to contribute from one to fifteen percent of their current compensation to the 401(k) Plan subject to the maximum permitted by law. Effective January 2001, the 401(k) provided for employer matching of 50% of employee contributions up to the first 3% of the participants contributions. The employer matching of 50% of the employee contributions was increased to the first 6% of the participants contribution as of January 1, 2003. Noven contributed $353,000, $274,000 and $148,000 for the year ended December 31, 2004, 2003 and 2002, respectively.

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12. SEGMENT, GEOGRAPHIC AND CUSTOMER DATA:

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

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

	2004	2003	2002
United States	$ 28,923	$ 22,130	$ 28,995
Other countries	16,968	21,036	26,377
Net revenues	$ 45,891	$ 43,166	$ 55,372

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

	2004	2003	2002
Novogyne	$ 24,002	$ 20,910	$ 29,899
Novartis Pharma/Novartis	14,170	18,701	23,201
P&G Pharmaceuticals	4,371	614	
Other	3,348	2,941	2,272
Net revenues	$ 45,891	$ 43,166	$ 55,372

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

2004	First	Second	Third	Fourth	Full Year
Net revenues	$ 11,130	$ 11,955	$ 10,101	$ 12,705	$ 45,891
Gross profit (product revenues less cost of products sold)	4,157	5,083	4,078	3,452	16,770
(Loss) income from operations	(547)	484	(1,982)	653	(1,392)
Equity in earnings of Novogyne[1]	637	8,228	6,232	2,544	17,641
Net income	$ 158	$ 5,678	$ 2,634	$ 2,754	$ 11,224
Basic earnings per share	$ 0.01	$ 0.24	$ 0.11	$ 0.12	$ 0.48
Diluted earnings per share	$ 0.01	$ 0.23	$ 0.11	$ 0.11	$ 0.46

2003	First	Second	Third	Fourth	Full Year
Net revenues	$ 10,025	$ 12,261	$ 9,096	$ 11,784	$ 43,166
Gross profit (product revenues less cost of products sold)	4,833	4,800	4,047	3,954	17,634
(Loss) income from operations	(934)	774	(1,547)	1,451	(256)
Equity in earnings of Novogyne[1]	1,525	3,795	4,529	7,245	17,094
Net income	$ 473	$ 3,050	$ 2,011	$ 5,662	$ 11,196
Basic earnings per share	$ 0.02	$ 0.14	$ 0.09	$ 0.25	$ 0.50
Diluted earnings per share	$ 0.02	$ 0.13	$ 0.09	$ 0.24	$ 0.49

[1]Equity in earnings of Novogyne is typically lower in the first quarter of each year than any other quarter due to Novartis preferred return of $6.1 million, which must be distributed before any allocation of income between Novartis and Noven. Furthermore, Equity in earnings of Novogyne fluctuates from quarter to quarter depending on Novogyne s results. In the fourth quarter of 2004, Novogyne recorded $1.0 million in expenses related to product liability insurance and $0.9 million of expenses related to accruals related to HT litigation, which are net of estimated insurance recovery. These expenses caused Noven s equity in earnings of Novogyne to be significantly lower than the third quarter of 2004. See Note 6 Investment in Vivelle Ventures LLC (d/b/a Novogyne).

14. COMMITMENTS AND CONTINGENCIES:

HT STUDIES:

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with the use of oral combination hormone therapy (HT). The study revealed an increase in the risk of developing breast cancer and increased risks of stroke, heart attack and blood clots. The WHI study was followed by the publication during 2002 2004 of the results of a number of other studies that found that the overall health risks from the use of certain HT products exceed the benefits from the use of those products. In the first quarter of 2004, the NIH discontinued the estrogen-only arm of the WHI study because results were showing an increased risk of stroke and because,

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after nearly seven years of follow-up, the NIH determined that it had sufficient data to assess the risks and benefits of estrogen use in the trial. Researchers continue to analyze data from both arms of the WHI study and other studies, and other publications may be forthcoming.

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

PRODUCTION ISSUES:

Noven maintains in-house product stability testing for its commercialized products. This process includes, among other things, testing samples from commercial lots under a variety of conditions to confirm that the samples remain within required specifications for the shelf life of the product.

In 2003, Noven s product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot patches did not maintain required specifications throughout the products shelf lives, resulting in product recalls of certain lots. As a result, in 2003, Noven and Novogyne established allowances for the return of recalled product, which had the effect of reducing Noven s and Novogyne s net revenues by $1.4 million and $6.5 million, respectively, for the year ended December 31, 2003. Based on a review of available relevant information, including actual product returns and future expected returns, Noven and Novogyne reduced these allowances during the year ended December 31, 2004, which had the effect of increasing net revenues for the year ended December 31, 2004 by $0.6 million and $3.3 million for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase Noven s income before income taxes by $2.2 million for the year ended December 31, 2004. The effect on Novogyne of Novogyne s adjustment was to increase Novogyne s income before income taxes by $2.8 million for the year ended December 31, 2004. At December 31, 2004, Noven s allowances for recall related returns and reserves for expected costs related to the 2003 product recalls were immaterial. There are no remaining allowances at Novogyne related to the 2003 recall.

As a result of the 2003 recall of Vivelle-Dot patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of Vivelle-Dot. In the first quarter of 2005, a total of ten lots of Vivelle-Dotmanufactured in 2003 were identified for recall when one of Noven s stability protocols revealed that these lots did not meet required specification or were associated with lots that did not meet specification. Because these lots were manufactured in 2003, Noven estimates that an immaterial number of patches from these lots currently remain in distribution. Marketing, general and administrative expense in 2004 includes an allowance of $0.3 million for estimated costs related to these recalls.

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Based on testing and analysis to date, Noven believes that the probable cause of the recent Vivelle-Dot stability failures remains related to the same problematic patch backing material that led to the 2003 recall. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot stability failures. If the root cause determination or additional testing (including Noven s routine stability testing) indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. The final field alert for the recall of the additional lots of Vivelle-Dot was submitted to the FDA on March 11, 2005, and Noven cannot predict what action, if any, the FDA may take as a result of the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, Novartis, as the holder of the Vivelle-Dot NDA, possesses the sole authority to initiate a recall and Novartis decision is not within Noven s control. Among others risks, the recent, or any additional, recalls of Vivelle-Dot could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot. Vivelle-Dot represented over 80 percent of the total prescriptions written for Noven s products in the fourth quarter of 2004 and Noven s and Novogyne s results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

In late October 2004, Noven s product stability testing program indicated that one commercial lot of CombiPatch® product did not maintain required specifications throughout the product s shelf life due to the formation of crystals. This issue is unrelated to the issue that led to the 2003 CombiPatch® recalls referenced above. Novartis has recalled the affected lot. The recall of this lot did not have a material impact on Noven s and Novogyne s financial statements for the year ended December 31, 2004. Noven continues to manufacture and ship CombiPatch® to Novogyne. Noven continues to maintain our stability testing for CombiPatch®, and are undertaking additional testing related to the October 2004 stability failure. If Noven s testing indicates that additional CombiPatch® lots do not meet specifications or are affected by the issue impacting the lot recalled, there could be additional recalls. Although Noven and Novartis work together in assessing production issues, the decision to recall product resides with Novartis as the holder of the CombiPatch® NDA and is not within Noven s control. If Noven s estimates concerning product returns associated with the recall are incorrect, or if Noven s continued testing indicates that more than one lot is affected, or if Novartis should initiate additional recalls for any reason, then Noven s and Novogyne s business and results of operations could be materially and adversely impacted.

The recent recalls may result in an FDA inspection of Noven s facilities and procedures and Noven cannot assure that the FDA will be satisfied with Noven s operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that Noven s manufacturing controls and procedures are not sufficient, Noven could be required to suspend production until Noven demonstrates to the FDA that Noven s controls and procedures are sufficient.

SUPPLY AGREEMENT:

Noven s supply agreement with Novogyne for Vivelle® and Vivelle-Dot™ patches expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement s commercial terms. There is no assurance that the agreement s non-

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commercial terms would be enforceable with respect to post-expiration occurrences. A decision to discontinue operating in accordance with the agreement under the agreement s commercial terms could have a material adverse effect on Noven s financial position and results of operations. Novogyne s designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

LITIGATION, CLAIMS AND ASSESSMENTS:

On August 7, 2003, an individual filed a lawsuit on behalf of a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. The complaint alleges that, during the subject period, Noven and its officers named as defendants violated the Securities Exchange Act of 1934 by making false and misleading statements in its public disclosures regarding Noven s Methylphenidate patch product. Following the filing of the Plaintiff s complaint, five other substantially similar complaints were filed against Noven and its officers named as defendants in the above referenced action. In December 2004, the court entered an order appointing Equitec-Cole Investor Group as the lead plaintiff and, on or about February 11, 2005, the Plaintiffs filed an Agreed Motion and Proposed Order of Voluntary Dismissal seeking that the complaint be dismissed without prejudice. Noven believes the lawsuit is without merit. If the lawsuit is not ultimately dismissed or if Plaintiffs decide to refile this lawsuit, Noven intends to vigorously defend the lawsuit. The lawsuit, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability, if any, with respect to the lawsuit is presently not determinable.

In July 2004, an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including CombiPatch®, which is manufactured by Noven and distributed by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount. In addition, Novartis has advised Noven that Novartis has been named as a defendant in at least 11 additional lawsuits alleging liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven products, Vivelle®, Vivelle-Dot™ and CombiPatch®. To date Noven has been named in one lawsuit and Novogyne has not been named in any, to Noven s knowledge. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. Novogyne has established an accrual for the expected legal fees and settlements of these lawsuits for $1.6 million with an offsetting insurance recovery of $0.7 million. This accrual represents Novartis management s best estimate as of December 31, 2004. The outcome of these product liability lawsuits cannot ultimately be predicted.

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

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CONTRACT AND LICENSE AGREEMENTS:

Noven is obligated to perform under its contract and license agreements. In certain circumstances, Noven is required to indemnify its licensees from damages caused by the products Noven manufactures as well as claims or losses related to patent infringement.

INTERNAL REVENUE SERVICE AUDIT:

Noven, from time to time, is subject to audits by taxing authorities, covering a wide range of matters and the Internal Revenue Service is currently auditing Noven s federal income tax returns for certain open years. Such matters are subject to various uncertainties, and it is possible that some of these matters may be resolved unfavorably to Noven. Since 2001, Noven has established accruals for pending matters that it believes are probable and reasonably estimable. In the fourth quarter 2004, the provision for income taxes benefited from a $0.4 million reduction in these accruals for ongoing tax audits due to the favorable resolution of certain tax matters. As of December 31, 2004, Noven had $1.1 million in accruals related to these matters. The outcome of the pending matters cannot ultimately be predicted.

FENTANYL INVENTORIES:

As of December 31, 2004, Noven had incurred $10.8 million for the cost of pre-launch inventories for its fentanyl patch. If approval is not ultimately received or is delayed, Noven s agreement with Endo provides that the parties will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula and Noven may be unable to recover its share of such costs, which could be up to approximately $6.0 million.

EMPLOYMENT AGREEMENT AND BONUS PLAN:

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

Noven has a formula bonus plan that includes company and individual performance goals. Noven incurred $3.8 million, $2.8 million and $2.5 million of bonus expenses in 2004, 2003 and 2002, respectively. Under the plan, a fixed percentage of each employee s base salary is set as a target incentive bonus award for such employee. To the extent that actual company performance is equal to, exceeds or is less than the company performance targets, an employee s bonus award may be equal to, greater than or less than his target award. An employee s non-financial goals are then considered in determining his or her final bonus award. In 2004, 2003 and 2002, Noven met or exceeded each of the company performance goals, and in accordance with the plan formula the bonus awards to most employees were greater than their initial target awards.

In September 2000, Noven entered into a Severance and Non-Competition agreement with Steven Sablotsky, then Co-Chairman of the Board of Directors. Pursuant to the agreement, Mr. Sablotsky s employment as an officer of Noven terminated on June 1, 2001. Noven paid Mr. Sablotsky $1.2 million on that date, which was 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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WAREHOUSE LEASE:

In February 2005, Noven entered into an Industrial Long-Term Lease (the Lease) for approximately 73,000 square feet of newly constructed space located in close proximity to its manufacturing facility in Miami, Florida. Noven intends to use the leased space for the storage and, as needed, the manufacture of new product. The lease term is 10 years, which may be extended for up to an additional 21 years pursuant to four renewal options of five years each and a one-time option to renew for one year. The annual base rent is $6.40 per square foot. Noven will also pay a monthly management fee equal to 1.5 percent of the base rent. The rent for the first year is discounted to $3.20 per square foot. The base rent is subject to annual increases of three percent during the initial 10 year term. After the initial term, the rent will be 95 percent of the fair market rate of the leased space as determined under the Lease. The landlord will reimburse Noven up to $912,300 for leasehold improvements. For accounting purposes, Noven expects to amortize the aggregate expected rental payments on a straight-line basis over the initial 10 year term of the Lease. The renewal terms have not been included for amortization purposes because Noven cannot reasonably estimate the rental payments after the initial term and Noven cannot assure that it will renew the Lease after the initial term. Any leasehold improvements will be recorded at cost and will be amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the initial 10 year lease term. Reimbursements of leasehold improvements by the landlord will be recorded as a deferred rent credit and will be amortized on a straight-line basis over the initial 10 year lease term as a reduction of rent expense.

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Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying balance sheets and the related statements of operations, members capital and cash flows present fairly, in all material respects, the financial position of Vivelle Ventures LLC at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 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 the standards of the Public Company Accounting Oversight Board (United States). 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, 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.

/s/ PRICEWATERHOUSECOOPERS LLP

Florham Park, New Jersey
March 14, 2005

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Balance Sheets
December 31, 2004 and 2003

	2004	2003
Assets		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation	$ 23,131,128	$ 21,332,627
Due from affiliate Novartis Pharmaceuticals Canada, Inc.		696,620
Finished goods inventory (net of reserves of $0 and $949,137 as of December 31, 2004 and 2003)	2,177,436	2,682,113
Insurance receivable (Note 7)	700,000	
Other current assets	290,499	265,521
Total current assets	26,299,063	24,976,881
Long-term assets (Note 3) (net of amortization of $23,172,993 and $16,993,528 as of December 31, 2004 and 2003)	38,621,652	44,801,117
Total assets	$ 64,920,715	$ 69,777,998
Liabilities and Members Capital		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc. (Note 6)	$ 10,682,732	$ 7,164,624
Accrued liabilities	1,182,936	173,250
Product liability reserve (Note 7)	1,600,000	
Allowance for returns (Note 4)	9,168,856	14,240,281
Total current liabilities	22,634,524	21,578,155
Commitments and contingencies (Note 7)		
Members capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	9,428,282	15,341,934
Total members capital	42,286,191	48,199,843
Total liabilities and members capital	$ 64,920,715	$ 69,777,998

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Statements of Operations
Years Ended December 31, 2004, 2003 and 2002

	2004	2003	2002
Net sales			
Third parties	$ 101,834,528	$ 98,572,264	$ 97,755,546
Novartis Pharmaceuticals Canada, Inc.	3,578,932	2,505,148	4,729,216
	105,413,460	101,077,412	102,484,762
Cost of sales			
Third parties	14,882,911	15,454,422	19,550,963
Noven royalties	5,203,932	4,978,247	4,504,663
Novartis Pharmaceuticals Canada, Inc.	1,489,292	1,052,221	2,079,829
	21,576,135	21,484,890	26,135,455
Gross profit	83,837,325	79,592,522	76,349,307
Operating expenses			
Administrative expenses	3,359,684	2,652,908	2,195,203
Sales and marketing expenses	31,364,085	28,019,902	30,895,914
Amortization expense	6,179,465	6,179,465	6,179,465
Product liability expenses, net of insurance recoverable	900,000		
Income from operations	42,034,091	42,740,247	37,078,725
Other income			
Interest income	191,287	181,957	349,741
Net income	$ 42,225,378	$ 42,922,204	$ 37,428,466

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

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Vivelle Ventures LLC d/b/a
Novogyne Pharmaceuticals

Statements of Members Capital
Years Ended December 31, 2004, 2003 and 2002

	Total
Members capital at December 31, 2001	$ 57,403,166
Net income	37,428,466
Distributions to Novartis	(14,763,251)
Distributions to Noven	(11,727,983)
Members capital at December 31, 2002	68,340,398
Net income	42,922,204
Distributions to Novartis	(39,652,880)
Distributions to Noven	(23,409,879)
Members capital at December 31, 2003	48,199,843
Net income	42,225,378
Distributions to Novartis	(28,363,294)
Distributions to Noven	(19,775,736)
Members capital at December 31, 2004	$ 42,286,191

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Statements of Cash Flows
Years Ended December 31, 2004, 2003 and 2002

	2004	2003	2002
Operating activities			
Net income	$ 42,225,378	$ 42,922,204	$ 37,428,466
Adjustments to reconcile net income to net cash provided by operating activities			
Amortization of license/marketing rights	6,179,465	6,179,465	6,179,465
Obsolescence reserve		(26,487)	725,624
Changes in assets and liabilities, net of assets acquired			
Due from affiliate Novartis Pharmaceuticals Corporation	(1,798,501)	7,138,185	(11,977,785)
Due from Novartis Pharmaceuticals Canada, Inc.	696,620	(696,620)	876,263
Inventories	504,677	3,659,656	(1,064,501)
Insurance receivable	(700,000)		
Other current assets	(24,978)	(224,131)	308,017
Due to affiliate Noven Pharmaceuticals, Inc.	3,518,108	2,599,345	(2,095,479)
Product liability reserve	1,600,000		
Allowance for returns and other liabilities	(4,061,739)	1,511,142	6,111,164
Net cash provided by operating activities	48,139,030	63,062,759	36,491,234
Investing activities			
Cash paid to purchase the CombiPatch® license/ marketing rights and inventory (Note 3)			(10,000,000)
Net cash used in investing activities			(10,000,000)
Financing activities			
Distributions to members (Note 5)	(48,139,030)	(63,062,759)	(26,491,234)
Net cash used in financing activities	(48,139,030)	(63,062,759)	(26,491,234)
Net change in cash			
Cash and cash equivalents			
Beginning of year			
End of year	$	$	$

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements
December 31, 2004

1. Organization, Business and Basis of Accounting

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

The Company is a limited liability company between Novartis Pharmaceuticals Corporation (Novartis) and Noven Pharmaceuticals, Inc. (Noven) (collectively referred to as the Members), pursuant to a Formation Agreement dated as of May 1, 1998 (date of inception). On May 1, 1998, Novartis granted an exclusive sublicense to the Company of the license agreement between Noven and Novartis, assigned the Company certain of its rights and obligations under a supply agreement between Noven and Novartis, 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 products to the Company and for providing marketing and promotional services pursuant to certain other agreements, as amended. The Company has no discrete employees (Note 5).

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

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

2. Summary of Significant Accounting Policies

Use of Estimates

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

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.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2004

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

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

Sales Allowances
Novartis records the Company s sales net of sales allowances for chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances. Novartis maintains the reserves associated with such sales allowances on behalf of the Company and pays all moneys owed and issues credits to individual customers as deemed necessary. The contracts that underlie these transactions are maintained by Novartis for its business as a whole and allocated to the Company for its products. Based on an analysis of the underlying activity, the amounts recorded by the Company represent Novartis best estimate of these charges that apply to sales of the Company. Provision for sales returns are estimated based on historical experience and may vary in future periods.

The following table sets forth the reconciliation of the Company s third party gross sales to third party net sales by each significant category of sales allowances:

	Years Ended December 31,		
	2004	**2003**	**2002**
Gross sales	$ 121,212,227	$ 117,776,888	$ 125,505,478
Sales returns	6,224,072	7,925,829	14,272,112
Managed health care rebates	7,924,918	6,574,981	6,664,917
Cash discounts	2,425,331	2,362,639	2,509,380
Medicaid rebates	1,040,227	752,594	948,015
Chargebacks	860,412	838,245	2,309,408
Other deductions	902,739	750,336	1,046,100
Total sales allowances	19,377,699	19,204,624	27,749,932
Net sales	$ 101,834,528	$ 98,572,264	$ 97,755,546

Advertising Costs
Advertising costs are expensed as incurred.

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

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2004

Impairment of Long Lived Assets

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

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. The Company includes legal fees in connection with accruals for product liability claims. The accruals are adjusted as new information becomes available. Receivables for insurance recoveries related to product liability claims under the Company s third party insurance policy are recorded, on an undiscounted basis, when it is probable that a recovery will be realized.

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 transactions were 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, was $40,000,000, due in four quarterly installments of $10,000,000 each, payable beginning June 1, 2001. In 2002 and 2001, the Company paid $10 million and $30 million respectively, directly to Aventis. The Company has allocated $3,477,267 to the value of the inventory and the remaining $61,794,645 to an intangible asset representing license and marketing rights. This intangible asset is being amortized over a period of ten years.

The accumulated amortization for this intangible asset was $23,172,993 and $16,993,528 as of December 31, 2004 and 2003. Amortization expense is $6,179,465 per year, and will total $30,897,325 over the next five years.

4. Allowance for Returns

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

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2004

The activity for the returns reserve for the three years ended December 31, 2004 is as follows:

Balance December 31, 2001	$ 6,673,109
Additions charged to expense	14,272,112
Deductions and adjustments	(8,165,215)
Balance December 31, 2002	12,780,006
Additions charged to expense	7,925,829
Deductions and adjustments	(6,465,554)
Balance December 31, 2003	14,240,281
Additions charged to expense	6,224,072
Deductions and adjustments	(11,295,497)
Balance December 31, 2004	$ 9,168,856

Product Recall

In October 2003, product stability testing revealed that certain CombiPatch® and Vivelle-Dot ™ products did not maintain the required specifications, resulting in a product recall. As a result, in 2003, the Company recorded a $6,500,000 estimated returns reserve related to the announced recall. Through December 31, 2004, $3,155,101 of actual CombiPatch® and Vivelle-Dot ™ returns associated with the recall were processed. The remaining recall reserve of $3,344,899 was reversed to income in 2004, as the United States Food and Drug Administration (the FDA) closed out the recall. In addition to the returns reserve, the Company recorded $432,661 in inventory provisions in 2003 related to product that was affected by the recall. The inventory related to the recall provision of $432,661 was destroyed in 2004 and the inventory provision was reduced to zero.

As a result of the 2003 recall of Vivelle-Dot ™ patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of Vivelle-Dot ™ . In the first quarter of 2005, a total of ten lots of Vivelle-Dot ™ manufactured in 2003 were identified for recall when one of Noven s stability protocols revealed that these lots did not meet required specification or were associated with lots that did not meet specification. Because these lots were manufactured in 2003, the Company estimated that an immaterial number of patches from these lots currently remain in distribution. The effect of these recalled lots to the Company s results of operations was immaterial.

Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot™ stability failures remains related to certain patch backing material that Noven obtained from a raw material supplier. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot™ stability failures. If the root cause determination or additional testing (including Noven s routine stability testing) indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. The final field alert for the recall of the additional lots of Vivelle-Dot™ was submitted to the FDA on March 11, 2005 and the Company cannot predict what action, if any, the FDA may take with respect to the recalls of Vivelle-Dot™.Although Noven and Novartis are working together in assessing the Vivelle-Dot™ production issues, the decision to recall product resides with Novartis as the holder of the Vivelle-Dot™ NDA and is not within the Company s control. Among others risks, the recent, or any additional, recalls of Vivelle-Dot™

could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2004

and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot™. Novogyne s results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

5. Operating Agreement

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

Management Committee
The Operating Agreement, as amended, provides for the formation of a Management Committee. The Members act on any matters to be determined by them through their representatives on the Management Committee. The Management Committee has general management powers with respect to the management and operation of the business and affairs of the Company and is responsible for policy setting and approval of the overall direction of the Company. The Management Committee consists of five individuals of whom three are designated by Novartis and two by Noven. A decision by the Management Committee is made by the affirmative vote of a majority of the Committee members. The Operating Agreement, as amended, also provides for certain actions or

decisions to require the vote of at least four of the five members of the Management Committee. Those actions or decisions include but are not limited to approval of material amendments to the annual operating and capital budget for activities outside normal business, amendments to the documents concerning the formation of the Company, incurrence of indebtedness in excess of $1 million, admitting a new member, acquiring or disposing of assets with a value in excess of $500,000 or settlement of litigation in excess of $1 million. The Members have further agreed that the approval of both Members is required to adopt or materially amend the annual sales and marketing plan or to enter into any contract with a third party sales force.

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.

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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 net income attributable to Vivelle-Dot™ and CombiPatch®, are to be allocated to the members in proportion to their respective percentage interests.

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

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

Distributable funds are payable to the Members quarterly or as determined by the Management Committee. Distributions are made to the Members based on taxable income. Commencing in 2002, the state of New Jersey enacted legislation that requires the Company to remit estimated tax payments on behalf of its owners, Novartis and Noven. Included in the 2004 distributions to Novartis and Noven of $28,363,294 and $19,775,736, respectively, are payments related to New Jersey state taxes of $2,497,347 and $1,692,966, respectively. Included in the 2003 distributions to Novartis and Noven of $39,652,880 and $23,409,879, respectively, are payments to New Jersey for state taxes of $2,514,880 and $1,670,879, respectively.

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

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

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6. Transactions with Affiliates

Services

The Company relies on Novartis and Noven for providing certain services as follows:

Novartis is responsible for providing the following services:

- Shipment of the products, fulfillment of product orders, inventory control and distribution, processing of invoices and cash management.
- Management of the overall marketing and sales program for the products in the managed care sector of the market, including but not limited to all corporate, institutional and government accounts.
- Customer service support and assistance for the products.
- Regulatory affairs support and assistance for the products.
- Bookkeeping and accounting, administrative functions relating to the distribution and sale of the products, and assistance with tax matters, insurance coverage and treasury services.
- Legal services.

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

During the years ended December 31, 2004, 2003 and 2002, Novartis charged the Company $2,796,760, $3,205,708 and $2,324,055, respectively, for these services.

Bookkeeping, Accounting and Treasury

The books and records of the Company are maintained by Novartis. The Company s transactions are initially

recorded in Novartis general ledger and are transferred to the Company s ledger on a monthly basis with the corresponding entry being recorded as an amount due to or from Novartis. The balances in this account of $23,131,128, $21,332,627 and $28,470,812 as of December 31, 2004, 2003 and 2002, respectively, represent the net balance of these transactions for the period from commencement of the Company to those dates.

The Company received interest on amounts due from Novartis during the year ended December 31, 2004, 2003 and 2002 at an average annual rate of 1.4%, 1.2% and 2%, respectively. During these periods, interest of $191,287, $181,957 and $349,741, respectively, was earned and is reflected in the amount 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 Corporation and Novartis Pharmaceuticals Canada, Inc. on the financial statements, respectively.

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

	Years Ended December 31,		
	2004	**2003**	**2002**
Balance at the beginning of the period	$ 21,332,627	$ 28,470,812	$ 16,493,027
Net sales (excluding returns)	108,058,600	106,498,093	112,027,659
Sales returns processed	(11,295,497)	(6,465,554)	(8,165,215)
Copromotion income	945,000	900,000	
Interest income on cash balances	191,287	181,957	349,741
Distributions to members	(48,139,030)	(63,062,759)	(26,491,234)
Payment to Noven for marketing services, inventory purchases and royalties	(48,114,238)	(42,717,694)	(58,528,474)
Disbursements made on behalf of the Company	(1,209,814)	(1,608,162)	(804,134)
Novartis service charges	(2,796,760)	(3,205,708)	(2,324,055)
Cash received from Novartis Canada	4,262,142	1,808,528	5,605,479
Payment for CombiPatch® license			(10,000,000)
Other	(103,189)	533,114	308,018
Total	$ 23,131,128	$ 21,332,627	$ 28,470,812

Noven is responsible for providing the following services:

Manufacturing and packaging products for distribution by Novartis.

Retention of samples and regulatory documentation of the products.

Design and implementation of an overall marketing and sales program for the products in the hospital and retail sales sectors of the market, including the preparation of annual and quarterly marketing plans and field sales force staffing.

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

During the years ended December 31, 2004, 2003 and 2002, Noven charged the Company $20,014,190, $18,652,109 and $18,344,551, respectively, for field sales force staffing and marketing.

Noven also provides advertising and other services in connection with the marketing and promotion of the products. Such costs charged during the years ended December 31, 2004, 2003 and 2002 were $10,663,298, $8,835,488 and $11,599,911, respectively.

Royalties
Royalties are payable to Noven by the Company on the sale of Vivelle® and Vivelle-Dot™ in the United States of America. The royalty formula is based upon a percentage of the products net sales. In addition, a minimum annual royalty formula is specified.

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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, 2004, 2003 and 2002, the Company purchased products from Noven in the amounts of $15,216,288, $12,410,859 and $21,983,870, 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 (Note 7).

Due to Affiliate-Noven Pharmaceuticals, Inc.

The following represents the amounts payable to Noven related to:

	December 31,	
	2004	**2003**
Purchases of inventory	$ 794,745	$ 1,353,721
Services provided by Noven	8,594,065	4,255,330
Royalties	1,293,922	1,555,573
	$ 10,682,732	$ 7,164,624

7. Commitments and Contingencies

Litigation, Claims and Assessments

As of December 31, 2004, Novartis has been named as a defendant in 12 lawsuits that include 22 plaintiffs that allege personal injury liability arising from the use of hormone therapy (HT) products sold by the Company, including Vivelle®, Vivelle-Dot™ and Combipatch®. Noven has been named as a defendant in one of these lawsuits but in this lawsuit, in January 2005, the plaintiffs agreed to substitute Aventis for Noven and Novartis. The parties are in the process of drafting the necessary documents to effect the substitution of Aventis and dismissal without prejudice of Noven and Novartis. To date, Novogyne has not been named as a party to these lawsuits.

The Company s operating agreements contain a number of indemnification provisions in which the joint venture has indemnified the members relating to product liability losses. Novartis and Noven will seek indemnification and defense from the Company for any expenses and damages, including attorneys fees, incurred related to the aforementioned lawsuits and to any future lawsuits based on product liability theories related to Vivelle®, Vivelle-Dot™ and/or CombiPatch® to the extent that indemnification is permitted by the agreements between and among Novartis, Noven and the Company.

Although it is not possible to predict the ultimate outcome of its litigation at this time, the Company has established reserves in the amount of $1,600,000 for expected defense and settlement expenses related to 12 pending lawsuits against Novartis as well as for estimated future cases alleging use of the Company s products. These reserves represent management s best estimates at this time based on all available information relating to the pending claims and historical experience.

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For the year ended December 31, 2004 the Company had a claims-made insurance policy with a $50,000 deductible per claim and a $10,000,000 aggregate limit, including defense costs. The Company also purchased the optional 5 Year Extended Reporting Period Endorsement which permits coverage for an occurrence prior to the expiration of the current policy term (January 1, 2005) to be reported under the 2004 policy during the next five years, as long as policy limits have not been eroded by prior claims. The premium in the amount of $965,909 for this coverage was recognized in administrative expenses as of December 31, 2004. In addition, the 2005 limited exclusion (as discussed below) would not apply for occurrences prior to policy expiration, but reported within the extended reporting period of 5 years.

The Company obtained a claims-made insurance policy for 2005 with a $150,000 deductible per claim and a $5,000,000 aggregate limit, including defense costs. This policy contains a limited HT exclusion providing no coverage for claims reported after January 1, 2005 for products which do not have the new labeling required by the FDA.

To the extent insurance coverage provides for recovery of claims, the Company will establish an insurance receivable, using estimates consistent with those used to develop the liability. The Company recorded an insurance receivable of $700,000 as of December 31, 2004.

Novartis and Noven intend to vigorously defend themselves in the HT litigation. Given the unpredictable nature of litigation, no assurance can be given that the Company s actual liability with respect to HT litigation will not exceed the reserved amounts. The Company s financial condition, results of operation and/or cash flows could be materially and adversely affected if and to the extent that the Company s estimate of the HT litigation liability proves incorrect or the Company is unable to recover payments under its product liability insurance policy.

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

Supply and Other Agreements
On December 17, 2004, Novartis and Noven entered into an amendment to the existing joint venture agreements to address product development and commercialization of a next generation estrogen patch. The agreement requires the Company to reimburse Noven for development costs up to $9,400,000 if the product receives FDA approval prior to a specified date and Novartis chooses not to launch and commercialize the product. This amount will be expensed by the Company when and if Novartis chooses not to commercialize the product.

The Company has a supply agreement with Noven for the purchase of the Vivelle® and Vivelle-Dot™ products which expired in January 2003. The Company is obligated to purchase a nominal amount of inventory in the subsequent fiscal year. The Supply Agreement expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement s original commercial terms. A decision to discontinue operating in accordance with the Supply Agreement could have a material adverse impact on the Company s financial position, results of operations and cash flows.

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HT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with use of oral combination HT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin after an average follow-up period of 5.2 years because the oral combination HT product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, the National Cancer Institute published the results of an observational study in which it found that postmenopausal women who used estrogen therapy (ET) for 10 or more years had a higher risk of developing ovarian cancer than women who had never used HT. Since 2002, several other published studies have identified increased risks from the use of HT. As a result of the findings from the WHI and other studies, the FDA has required that black box labeling be included on all HT products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention. Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage, including a new five-year study aimed at determining whether ET used by women aged 40 to 55 reduces the risk of heart disease. This study also seeks to determine if transdermal estrogen patches (as well as alternative dosage forms such as gel and a cream) are more or less beneficial than a conjugated oral product. The study sponsor s website indicates that Vivelle-Dot™ will be used as the estrogen patch in the study. The Company is not a sponsor of this study and has not reviewed the protocol. Among other risks related to this study, the market for Vivelle-Dot™ would likely be adversely affected if this study finds the Company s transdermal estrogen patch is less beneficial than other dosage forms, and the Company could be subject to an increased risk of product liability claims if its products are found to increase the risk of adverse health consequences.

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