NOVEN PHARMACEUTICALS INC
Form 10-K
March 15, 2006

Table of Contents

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, 2005 **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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o

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

As of March 1, 2006, there were 23,665,011 shares of Common Stock outstanding.

The aggregate market value of such voting stock held by non-affiliates of the registrant was approximately $409 million (computed by reference to the price at which the voting stock was last sold on June 30, 2005, 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 2006 Annual Meeting of Shareholders.

NOVEN PHARMACEUTICALS, INC.
Annual Report on Form 10-K
for the year ended December 31, 2005
TABLE OF CONTENTS

Table of Contents

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 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 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 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 Risk Factors beginning on page 21 of this report.

PART I

Item 1. Business.

General

Noven Pharmaceuticals, Inc. (we or Noven) develops and manufactures 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 prescribed 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 primarily under the brand name Estraderm® outside the United States.

Vivelle® (estradiol transdermal system), an estrogen patch utilizing a previous 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.

Table of Contents

CombiPatch® (estradiol/norethindrone acetate transdermal system), the first combination estrogen/progestin transdermal patch approved by the FDA. 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 products that we are exploring consist of third-party proprietary and non-proprietary molecules, which are generally FDA-approved compounds as opposed to new chemical entities, as well as generic versions of existing transdermal products where we believe our proprietary technology may be beneficially applied.

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) with the proposed brand name Daytrana (methylphenidate transdermal system). We believe that this product, if approved by the FDA, may address several issues associated with existing ADHD therapies. We have licensed the exclusive global rights to market our methylphenidate patch to Shire plc (Shire). In December 2005, we received an approvable letter from the FDA for Daytrana. The approvable letter contains proposed revisions to labeling, as well as requests for data clarification, post-marketing surveillance, and post-marketing studies. In February 2006, we provided the FDA with a resubmission to the Daytrana NDA intended to address the issues presented in the approvable letter. In March 2006, the FDA advised us that our resubmission was complete and that April 9, 2006 had been established as the user fee goal date for the FDA to complete its review of the resubmission.

We are working with Procter & Gamble Pharmaceuticals, Inc. (P&G Pharmaceuticals) to develop prescription transdermal patches 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 sexual 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 indicated that it is working to identify a clinical strategy intended to address the FDA s safety concerns related to this product.

We have an active research and development program investigating a broad range of products and therapeutic categories where we believe our technology may be beneficially applied. We are also investigating ways to improve our existing technology and to acquire new technologies that we believe will expand the range of molecules we can deliver through transdermal or other delivery systems. 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 as Noven Pharmaceuticals, Inc., and our principal executive offices are located at 11960 S.W. 144th Street, Miami, Florida 33186; our telephone number is (305) 253-5099.

Novogyne Pharmaceuticals

Our menopausal hormone therapy products are marketed and sold in the United States 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

Table of Contents

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 2005, 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 Vivelle-Dot to become the most prescribed product in the transdermal estrogen therapy (ET) category, with a greater than 45% share of monthly total prescriptions written in the United States as of December 2005. Effective January 1, 2006, the Novogyne sales force, formerly a contract sales force, became direct employees of Noven. As is the case with other costs incurred by Noven on behalf of Novogyne, the terms of the joint venture provide that we will be reimbursed by Novogyne for costs associated with these sales force employees.

Under the terms of the joint venture agreements, we manufacture and supply Novogyne with Vivelle-Dot, Vivelle® 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-Dot, Vivelle® 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-Dot and Vivelle® 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 the other party s entire interest in 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 also pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount

Table of Contents

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 entire interest in Novogyne or to sell its entire 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;
- seeking to license developmental products at various stages of development to strategic industry partners for completion of development and commercialization;
- developing and/or acquiring new technologies that we believe will permit us to expand the number of compounds that our products can deliver and the therapeutic areas our products can address;
- identifying opportunities 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 we believe may offer desirable financial return. We generally seek to develop and commercialize products through agreements with strategic industry partners. We believe that the introduction of our products in diverse therapeutic categories with multiple partners will 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.

Table of Contents

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 Daytrana, use a patented blend of silicone adhesive, acrylic adhesive 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 adhesive, acrylic adhesive 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-Dot/Estradot® our advanced estrogen patch;

Vivelle®/Menorest/Femiest® our original 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 $43.8 million, $39.8 million and $41.2 million for 2005, 2004 and 2003 respectively, which represented 83%, 87% and 96% of our revenues in these years, respectively.

Table of Contents

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 a substantial percentage of menopausal women. Another common symptom associated with menopause is vaginal dryness. Moderate-to-severe menopausal symptoms can be treated by replacing the estrogen that the body can no longer produce. Estrogen therapy can effectively relieve hot flashes and night sweats, and can prevent 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 commenced a five-year study aimed at determining whether ET use by women aged 40 to 55 reduces the risk of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. While our products are not being used in the study, the market for our products could be adversely affected if this study finds that a transdermal estrogen patch is less beneficial than other dosage forms, and we could be subject to increased product liability risk if HT patch products are found to increase the risk of adverse health consequences. We are currently named as a defendant in one 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.

Table of Contents

Advanced Transdermal Estrogen Patch

Utilizing our proprietary DOT Matrix® technology, our advanced transdermal estrogen patch (marketed as Vivelle-Dot and Estradot®) is one-third the area of our original Vivelle® 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 original product, with a lower potential for skin irritation. Vivelle-Dot is the most prescribed transdermal ET product in the United States. This product is bioequivalent to Vivelle® and is currently 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.

Novogyne markets Vivelle-Dot in the United States and sanofi-aventis (Aventis) has marketing rights for Vivelle-Dot in Japan. In Canada, Vivelle-Dot is marketed as Estradot® by an affiliate of Novartis Pharma AG (Novartis Pharma). Novartis Pharma holds the rights to market Vivelle-Dot under the name Estradot® in all countries other than the United States, Canada and Japan, and has marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by us.

Under the terms of our license to Novartis Pharma, 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 the United Kingdom, France, Germany, Spain (without the benefit of government reimbursement) and in a number of smaller European countries. We cannot assure that Novartis Pharma will be successful in launching Estradot® in these or other countries. The price 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. The supply agreement for Vivelle-Dot and Vivelle® expired in January 2003. Since the expiration of the 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 as well as Novartis greater financial and business resources, we may be unable to negotiate

Table of Contents

favorable business terms with Novartis or resolve any dispute that we may be involved in with them in a favorable manner.

Original Transdermal Estrogen Patch

Our original 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 in Japan, and by Novartis Pharma in all other territories. Novartis Pharma is selling this product under the brand name Menorest in a number of foreign countries. Novogyne and Novartis Pharma s Canadian affiliate market this product under the brand name Vivelle® in the United States and Canada, respectively, and Aventis markets this product under the brand name Femiest® in Japan. This product is in the process of being discontinued in several jurisdictions (including certain dosage strengths in the United States) where our advanced generation ET patch has gained acceptance, and manufacturing of Vivelle® is expected to be discontinued by the end of 2006.

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. Vivelle® is supplied under the same agreement as Vivelle-Dot. 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 HT 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.

Novogyne acquired marketing rights to the product in 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 agreement with Novartis Pharma relating to future generations of combination estrogen/progestin patch products. Due to current regulatory requirements in Europe, Novartis Pharma has elected not to complete development of a next generation combination estrogen/progestin patch.

Estalis® is presently approved in one dosage strength in most European countries. Novartis Pharma has advised us that they may seek marketing approval and commercialization of a lower dosage strength when and if that dosage strength completes development. No assurance can be given

Table of Contents

of any growth in this market, that we will complete development of this product or that approval will be obtained, and the timing of any launch cannot be predicted.

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. Sales to Novogyne are at an agreed-upon price pursuant to a supply agreement.

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

Shire

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

Presently, all ADHD medications approved in the United States are delivered orally. Stimulant therapies, including methylphenidate, which is designated as a Schedule II controlled substance by the United States Drug Enforcement Administration (DEA), are the most prescribed drug type for the treatment of ADHD. 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 Daytrana, our methylphenidate transdermal system. In the second quarter of 2003, we licensed 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

Table of Contents

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 Daytrana would be adversely affected.

In 2004 and 2005, Noven and Shire conducted additional clinical trials that were intended to address clinical issues raised in the not approvable letter that we received from the FDA in April 2003 relating to our NDA for Daytrana. In June 2005, we submitted an amendment to the NDA that included these new trial results, and in December 2005, we received an approvable letter from the FDA for Daytrana. The approvable letter contains proposed revisions to labeling, as well as requests for data clarification, post-marketing surveillance, and post-marketing studies. In February 2006, we provided the FDA with a resubmission to the Daytrana NDA intended to address the issues presented in the approvable letter. In March 2006, the FDA advised us that our resubmission was complete and that April 9, 2006 had been established as the user fee goal date for the FDA to complete its review of the resubmission.

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 for 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 sexual 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 indicated that it is working to identify a clinical strategy intended to address the FDA s safety concerns related to this product.

Endo

In July 2003, we submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market a generic fentanyl patch. We entered into an agreement with Endo Pharmaceuticals Inc. (Endo) in the first quarter of 2004 granting Endo the exclusive right to market our fentanyl patch in the United States. We received an up-front payment of $8.0 million from Endo, of which $6.5 million was allocated to license revenue for the fentanyl patch and the remaining $1.5 million was allocated based on fair value to fund feasibility studies that seek to determine whether certain compounds identified by the parties could be delivered through our transdermal technology. Our agreement provides that Endo would fund and manage clinical development of those compounds proceeding into clinical trials.

In July 2005, the FDA issued a public advisory that it is investigating reports of death and other serious side effects from overdoses involving both the branded and generic fentanyl patches. In September 2005, the FDA advised us that it did not expect to approve our ANDA and was consequently ceasing its review of our ANDA, based on the FDA s assessment of potential safety concerns related to the higher drug content in our generic product versus the branded product. Due to the FDA s determination, Noven and Endo agreed in December 2005 to terminate the fentanyl portion of the 2004 license agreement as well as the fentanyl supply agreement. Noven is currently

Table of Contents

evaluating the feasibility of reformulating the fentanyl patch to address the FDA s concerns, and has granted Endo a right of first negotiation with respect to any reformulated fentanyl patch that it may develop. Noven and Endo continue to proceed with other areas of their development collaboration that are unrelated to fentanyl.

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 feasibility and/or 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, 2005, 2004 and 2003, we spent $13.2 million, $9.5 million and $7.7 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 previously received from 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.

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

Table of Contents

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 our other 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 infringing our patents.

In the market for HT products, Novogyne competes against Wyeth Pharmaceuticals, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Berlex Laboratories, Esprit Pharma, Inc., Solvay Pharmaceuticals, Inc., Barr Laboratories and others, including Novartis, Novartis Pharma and their affiliates. We expect increased competition in the HT market as new products continue to be introduced in this field. Most of our competitors are substantially larger and have greater resources and larger sales forces than we do, as well as greater experience in developing and commercializing pharmaceutical products.

If approved by the FDA, Daytrana will face a highly competitive market, with a product mix that includes generic oral methylphenidate, long-acting formulations, other stimulant medications, medications not containing Schedule II controlled substances, and a variety of other drug types. Other products which may have improved safety and efficacy profiles are also in development. Shire currently markets non-methylphenidate products for the treatment of ADHD and in 2005 licensed an amphetamine pro drug for the treatment of ADHD for which an NDA was filed in December 2005. We cannot assure that Shire will market Daytrana aggressively or effectively if it is approved, or that Daytrana 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, including Johnson & Johnson, Novartis and Eli Lilly & Company (Lilly). Strattera®, a non-stimulant, non-controlled substance therapy marketed by 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 Daytrana, would be adversely affected.

Dependence on Licensees and Joint Venture

During 2005, 50% and 32% of our revenues were attributable to 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

Table of Contents

dependent on sales to Novartis Pharma, Novogyne and possibly Shire 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 manufacturing revenue, 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-Dot, Vivelle® 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 to our detriment. Any reduction in the level of support and promotion that these companies provide to our products, whether as a result of their focus on other products or otherwise, could have a material adverse effect on our business, results of operations, financial condition and prospects. Because of the legal complexities inherent in attempting to establish damages in litigation arising under agreements such as our agreements with Novartis and Shire, those agreements may not, as a practical matter, provide us with an adequate remedy for our partner s breach.

Manufacturing

Our headquarters and manufacturing facility is located on a 15-acre site in Miami-Dade County, Florida. On this site, we conduct our manufacturing operations in a single facility comprised of two approximately 40,000 square foot buildings located on approximately 7 acres that we lease from Aventis. This facility has been inspected by the FDA, the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, and by the Florida Department of Health 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 sufficient 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 have expanded our manufacturing area to facilitate the manufacture and storage of Daytrana. 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, the manufacture of new products. If FDA approval for Daytrana or other products under development is ultimately not obtained or if such products are not successfully commercialized, we may be unable to recover our upfront costs to expand our manufacturing capabilities. For other products under development, unless our partner is responsible for pre-launch inventories, we may not recover our up-front costs for 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 Daytrana includes only one supplier of the active pharmaceutical compound. In addition, the DEA controls access to controlled substances (including methylphenidate, fentanyl and amphetamine), and we must receive authorization from the DEA to

Table of Contents

obtain these substances. Any curtailment in the availability of such raw materials could result in production or other delays, and, in the case of products for which only one raw material supplier exists, could result in a material loss of sales, with consequent adverse effects on our business and results of operations. In addition, because most raw material sources for transdermal patches must generally be approved by regulatory authorities, changes in raw material suppliers may result in production delays, higher raw material costs and loss of sales, customers and market share. Some raw materials used in our products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, there can be no assurance that such companies will not expand their restrictions to include our applications.

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 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. A decision to develop and commercialize products ourselves could result in substantial research, development, sales, marketing and other expenses that could adversely affect our results of operations over a period of years.

Under the Novogyne joint venture agreements, Novartis has responsibility for Novogyne s distribution function (including managing the relationships and agreements with wholesale drug distributors and other trade customers) and its managed care strategy and relationships, while Noven has responsibility for the day-to-day management of Novogyne s marketing efforts and sales force. Effective January 1, 2006, the Novogyne sales force, formerly a contract sales force, became direct employees of Noven. As is the case with other costs incurred by Noven on behalf of Novogyne, the terms of the joint venture provide that we will be reimbursed by Novogyne for costs associated with these sales force employees. 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 Vivelle-Dot to become the most prescribed transdermal estrogen therapy product in the United States. We also seek to use this expertise more broadly to help us identify and evaluate the commercial potential of new product development projects that may help advance our growth strategy.

Patents and Proprietary Rights

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained over 30 United States patents and over 275 foreign patents

Table of Contents

relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 130 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 17 years from the date of grant. Our patents filed after June 7, 1995 will have a term of 20 years computed from the effective filing date.

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

Although there is a statutory presumption as to a patent s validity, the issuance of a patent is not conclusive as to such validity, or as to the enforceable scope of the claims of the patent. We cannot assure that our patents or any future patents will prevent other companies from developing similar or functionally equivalent products. We cannot assure that we would be successful in any action to enforce our patent rights that we may elect to bring against an alleged infringer. Likewise, we cannot assure that we would be successful in the defense of an infringement action. 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 and technologies referred to in this Form 10-K are registered as follows:

- DOT Matrix® and DentiPatch® are registered trademarks of Noven;
- 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 in Japan;
- Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited;
- Concerta® is a registered trademark of Alza Corporation;
- Strattera® is a registered trademark of Lilly;
- Intrinsa is a trademark of P&G Pharmaceuticals;
- Vioxx® is a registered trademark of Merck & Co., Inc.;

17

Table of Contents

- Duragesic® is a registered trademark of Johnson & Johnson; and

- Ortho Evra® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.

Government Regulation

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the development, 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 that 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 Application (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials that demonstrate reasonable assurance of the safety and efficacy of the product; (iv) submission to the FDA of an 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 other products such as COX-2 inhibitors (including Vioxx®) and certain antidepressants, 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. In response to these concerns, during 2005, the FDA created an independent Drug Safety Oversight Board comprised of FDA representatives, medical experts and other third parties to oversee the management of drug safety issues. We believe these changes will make drug development more lengthy, risky and expensive.

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 already 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 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

Table of Contents

Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), the FDA may not finally approve the ANDA until the earlier of thirty months from the date of the legal action or a final determination by a court that the applicable patent is invalid or would not be infringed by the applicant s product. We are developing products for which we or a licensee may file an ANDA. There can be no assurance we will not be sued for patent infringement, that we would prevail in any litigation or that the costs of any such litigation would not be prohibitive.

The Hatch-Waxman Act further provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, the FDA cannot grant final approval to any other 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, we cannot assure that even if we are 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 can 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 prior to FDA approval, 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, generally at differing dosages. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population at a number of separate clinical test sites. From time to time, Phase IV trials are conducted after a product is already approved and on the market to learn more about the product s long-term risks, benefits and optimal use, or to test the product in different populations of people, such as children or adults. 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 complete its 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, dosage, 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.

Table of Contents

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. Product approvals may be contingent on an agreement to conduct specified post-marketing programs, and 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. As the FDA s approval process comes under greater scrutiny by the government and the public, especially with regard to safety issues, we expect that the scope and frequency of post-marketing programs required as a condition of approval will increase. The approvable letter we received from the FDA for Daytrana contains requests for data clarification, post-marketing surveillance, and post-marketing studies as well as proposed revisions to labeling.

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

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. Most foreign regulatory authorities 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 and manufacturing practices, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state,

Table of Contents

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.

Backlogs

There were no material backlogs at the date of this filing and for the years ended 2005, 2004 and 2003.

Employees

As of December 31, 2005, we had approximately 374 employees, approximately 252 of which were engaged in manufacturing, process development, quality assurance and quality control, 25 in research and development, 11 in clinical research and regulatory affairs, and 86 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. Novogyne s sales force, formerly a contract sales force, became direct employees of Noven on January 1, 2006, increasing the number of Noven employees by approximately 120 individuals.

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 Daytrana 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 our 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 1A. Risk Factors.

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 our behalf. The risks and uncertainties described below are not listed in order of priority and are not the only ones we face. If any of the following risks actually occurs, our business, financial condition and results of operations would suffer. 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

Table of Contents

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.

Publication of negative results of studies or clinical trials may adversely impact our products.

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies, the results of which, when published, may have dramatic effects on the markets for the pharmaceutical products that are the subject of the study and on other similar or related pharmaceutical products. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products and could also cause us to be a target for product liability or other lawsuits.

Currently, our liquidity, results of operations and business prospects are almost entirely dependent on sales, license royalties and fees associated with transdermal HT products. The market for HT products has been negatively affected by the WHI study and other studies that have found that the overall health risks from the use of certain 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 53% from the second quarter of 2002 (the quarter immediately preceding the WHI study) to the fourth quarter of 2005. In addition, a private foundation has commenced a five-year study aimed at determining whether ET use by women aged 40 to 55 reduces the risks of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. The market for HT products, including ours, both in the United States and abroad, could be further adversely impacted if this or other HT studies find unacceptable risks from HT use. 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.

The FDA s analysis of potential safety issues associated with certain patch products, including Duragesic® and Ortho Evra®, and the resulting media coverage of these issues, may adversely affect the public s and the medical community s perceptions of other transdermal products, including our products, and could ultimately impair the commercial acceptance of our current and future patch products.

A 2005 study by researchers at the M.D. Anderson Cancer Center found adverse chromosomal effects on 12 children treated with oral methylphenidate. The FDA has announced that the National Institutes of Health (NIH) and Duke University have or will undertake additional studies designed to examine the chromosomal effects of oral methylphenidate. Additionally, as part of an ongoing FDA inquiry into the possible side effects of ADHD medications, the FDA Drug Safety and Risk Management Advisory Committee met on February 9, 2006 to discuss the cardiovascular risks associated with ADHD products and recommended to the FDA that stimulant-based ADHD medications carry a black-box warning about possible cardiac events. Other related FDA Advisory Committee meetings are scheduled. We cannot predict what effect these events, as well as any other studies or FDA actions that may occur as a result of the ongoing public debate in the United States regarding the appropriateness of using methylphenidate and other medications to treat children with ADHD, will have on our partner s ability to successfully commercialize Daytrana.

Table of Contents

If we cannot develop, license or acquire new products and commercialize them on a timely basis our financial position and results of operations could be adversely affected and the price of our common stock could 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 developing a product with the expectation that a licensee will be identified to assist in completing 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.

If we undertake an acquisition of technology, we will incur a variety of costs, and we may never realize the anticipated benefits of the acquisition.

One of our current growth strategies is to expand our technological base, including through the acquisition of new transdermal technologies that allow for the delivery of additional molecules through the skin. We may seek to expand our technological base through the acquisition of other companies or through the license or purchase of rights to these technologies. If we undertake an acquisition, the process of integrating the acquired business, technology or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits of any acquisition for a variety of reasons, such as an acquired technology proving to not be safe or effective in later clinical trials or if the technology is later found to infringe upon the intellectual property rights of another. It is possible that we may fund any future acquisition by issuing equity or debt securities, which could dilute the ownership percentage of current stockholders or limit our financial or operating flexibility as a result of restrictive covenants related to new debt. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote time and resources to potential acquisitions that are never completed.

Table of Contents

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 Daytrana, we have granted the exclusive marketing rights to Shire and we are working jointly with Shire to obtain FDA approval of our methylphenidate patch. Failure of Novartis, Shire and our other partners to adequately support our products 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 from ours. Some of our partners, including Novartis and Shire, market and sell products competitive with ours. Shire has a portfolio of ADHD products and has licensed an amphetamine pro drug for the treatment of ADHD for which an NDA was filed in December 2005. 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 2005, 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 the other party s entire interest in 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, regulatory, compliance, 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

Table of Contents

estimating and recording sales allowances and returns for Novogyne (which include reserves and allowances related to product returns), and is primarily responsible for ensuring compliance with applicable regulations relating to sales and marketing activities.

Novartis is responsible for internal controls over financial reporting for Novogyne, so our ability to assess their effectiveness at maintaining those internal controls is necessarily limited. 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.

Because Novartis maintains the relevant data, we may have limited ability to accurately forecast the amount of sales allowances in any period. If Novartis materially changes the assumptions it uses in determining the 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. More generally, any material errors by Novartis in performing its accounting functions for Novogyne could lead to a subsequent restatement of Novogyne s financial statements and in turn require us to restate our financial statements as well.

We may be unable to obtain marketing approval for our new products, including Daytrana, 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 and is likely to involve the expenditures of substantial resources. The process is subject to the broad authority and discretion of the FDA. In September 2005, the FDA advised us that it did not expect to approve our ANDA for our fentanyl patch and was consequently ceasing its review of our ANDA, based on the FDA s assessment of potential safety concerns related to the higher drug content in our generic product versus the branded product. Due to the FDA s determination, Noven and Endo agreed in December 2005 to terminate the fentanyl portion of the 2004 license agreement as well as the fentanyl supply agreement. Noven is currently evaluating the feasibility of reformulating the fentanyl patch to address the FDA s concerns.

In December 2005, we received an approvable letter from the FDA for Daytrana. The approvable letter contains proposed revisions to labeling, as well as requests for data clarification, post-marketing surveillance, and post-marketing studies. We cannot assure that the results of any post-marketing studies will be favorable or that the FDA will not take actions that will limit the marketability of Daytrana as a result of these studies. We also cannot be certain that the labeling that is ultimately approved for Daytrana will not restrict or otherwise adversely impact the marketability of the product.

We cannot assure that we will obtain the necessary regulatory approval for our 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.

Table of Contents

As a result of the publicity surrounding COX-2 inhibitors, certain antidepressants, and the publicity surrounding HT products, both citizen s groups and interests in the United States Congress have called for investigation and possible reform of the FDA approval process. In response to these concerns, during 2005, the FDA created an independent Drug Safety Oversight Board comprised of FDA representatives, medical experts and other third parties to oversee the management of drug safety issues, and the FDA may impose more stringent standards in approving or monitoring new products compared to the standards applied in the past. We believe these changes will make drug development more lengthy, risky and expensive.

Due to the diversity of proposals put forth, we cannot predict what effect future changes in regulations or legal interpretations, if, when and as ultimately promulgated may have on our business.

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, our success will depend on their market acceptance. Substantially all of our revenues are generated through sales of transdermal delivery systems, which generally are more expensive than oral formations. Our products are marketed primarily to physicians, some of whom are reluctant to prescribe a transdermal delivery system when an alternative delivery system is available. We and our licensees must demonstrate to prescribing physicians the benefits of transdermal delivery, especially with respect to products such as 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 Daytrana, the market for this product may be negatively affected by the outcome of the FDA s ongoing inquiry into the possible side effects of ADHD medications, the FDA Drug Safety and Risk Management Advisory Committee s recent recommendation that ADHD medications carry a black-box warning about possible cardiac events, a 2005 study by researchers at the M.D. Anderson Cancer Center that found adverse chromosomal effects on 12 children treated with oral methylphenidate, 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, non-Schedule II products 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 that supply agreement, the parties have continued to operate in accordance with the supply agreement s

Table of Contents

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 the discretion of Noven (if we have regulatory authority for the product), our partners (if they have regulatory authority for the product), the FDA, other government agencies, or a combination of these parties. 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. We have experienced a number of production issues, some of which have led to recalls in the past. Among other risks, the past recalls of our products, or any further impact of the issues causing these recalls, could result in a decision to: recall all or a significant portion of an affected 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 the affected product. 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 our reputation and the reputation of the product. In these cases, our business, results of operations and financial condition could be materially and adversely affected.

Failure to comply with applicable regulations may result in product recalls and/or penalties.

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the development, 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. In addition, 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 or other negative written observations, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales, withdrawal of previously approved marketing applications, and criminal prosecution. Under the terms of the Novogyne joint venture, Novartis is responsible for providing

Table of Contents

regulatory services. There can be no assurance that Novartis will comply with these regulations or that any violation by Novartis will not have an adverse effect on us.

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

Our developmental methylphenidate patch is a new product 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. If we do not adequately and timely scale-up our manufacturing processes for new products or otherwise meet supply requirements, the success of our new product launches and revenues could be adversely affected. It may also result in Shire or, if permitted under our agreements, our 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 applicable transaction. In addition, the active ingredient in our methylphenidate patch is 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.

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 Daytrana includes only one supplier of the active pharmaceutical compound. In addition, 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. In December 2005, the DEA granted us procurement quota of methylphenidate raw material sufficient to manufacture launch supplies of Daytrana. Our application for additional procurement quota is currently pending at the DEA. We cannot guarantee the timing or quantity of future DEA awards of methylphenidate procurement quota necessary for the ongoing production of Daytrana, and the timing of any future award may impact the success of product launch and market penetration.

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 this new supplier 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.

Table of Contents

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 as well as products using other drug delivery systems, 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. 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, Cephalon and Lilly. Johnson & Johnson markets Concerta®, the market-leading methylphenidate product, and Novartis and Lilly market competitive ADHD products. Strattera®, a non-stimulant, non-controlled substance therapy, has gained significant market share since being launched by Lilly in 2003. 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 Daytrana would be adversely affected. Shire has licensed an amphetamine pro drug for the treatment of ADHD which, although a stimulant, may not be designated as a Schedule II controlled substance. 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 Daytrana and therefore may decrease the likelihood that we will receive the sales-based milestone payments.

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.

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 in the FDA Orange Book with respect to a reference listed 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. 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

Table of Contents

labeling for the branded product, filing a citizen petition with the FDA, pursuing state legislative efforts to limit the substitution of generic versions of brand pharmaceuticals, filing patent infringement lawsuits that automatically delay FDA approval of many generic products, introducing a second generation product prior to the expiration of market exclusivity for the first generation product, which may reduce demand for a generic first generation product, and obtaining market exclusivity extensions by conducting pediatric trials of brand drugs.

The European market 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 Estradot® in the United Kingdom, France, Germany, Spain (without the benefit of government reimbursement) and in a number of smaller European countries. We cannot assure that Novartis Pharma will be successful in launching Estradot® in other countries. The profitability of sales in Europe may 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. Lack of government reimbursement for Estradot® could also negatively impact the product s profitability. 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 2005, 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 Estradot® launches and commercialization efforts by Novartis Pharma, the impact of the HT studies on prescriptions for our HT 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 for Daytrana, and any subsequent launch of new products, and the success of Shire s commercialization efforts. Our earnings may fluctuate because of, among other things, fluctuations in research and development

Table of Contents

spending resulting from the timing of clinical trials. In addition, 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 we or Novogyne fail to realize the full value of our intangible assets.

Accounting principles generally accepted in the United States require Novogyne and us to test the recoverability of our respective long-lived assets and certain identifiable intangible assets whenever events or changes in circumstances indicate that those assets 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 or a recall of CombiPatch® 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.

Table of Contents

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 depends, 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 Daytrana, 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 Daytrana. 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, some parties have advocated for the re-importation of prescription drugs from Canada and other countries for re-sale in the United States at a discount to United States prices. 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. We have been named as a defendant in one case in which a plaintiff alleges personal injury from the use of HT products, including Vivelle®, which we manufacture and Novogyne distributes. In addition, Novartis has advised us that Novartis has been named as a defendant in at least 16 additional lawsuits involving approximately 21 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 our products, Vivelle-Dot, Vivelle® 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

Table of Contents

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. Over the past few years, the cost of our product liability insurance policy has increased while providing significantly less coverage and higher deductibles than in the past. 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 cannot cover all potential exposure 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.

We use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We cannot eliminate all risk of accidental contamination from or discharge of hazardous materials and any resultant injury. Compliance with environmental laws and regulations may be expensive. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks.

Our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades.

Our business depends on the efficient and uninterrupted operation of our computer and communications software and hardware systems, and our other information technology. In the coming years, we may have to implement significant upgrades to our information systems, including the implementation and qualification of an upgrade to our business applications software. If our systems were to fail or we are unable to successfully expand the capacity of these systems or to integrate new technologies into our existing systems, our operations and financial results could suffer.

Table of Contents

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 last few years. 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, it is possible that, in some cases, coverage may not be available at any price.

Our financial position and results of operations could be harmed if we are required to perform under existing or future contractual indemnification provisions.

In the normal course of business, we enter into development, license, supply, employment and other agreements that include indemnification provisions. The Novogyne joint venture operating 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 they relate to potential damages, settlement amounts and defense costs associated with the product liability lawsuits that claim the use of products we manufacture and Novogyne distributes. While insurance coverage may mitigate the costs of some of our obligations under our 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 us. 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

Table of Contents

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.

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 other party s interest in the joint venture. As a result of the buy/sell provision, any potential acquirer of us 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 us by a third party, which could have an adverse effect on the market price for our common stock. In addition, 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-Dot and Vivelle® 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. During 2005, our common stock traded as low as $10.44 per share and as high as $19.20 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.

Table of Contents

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our headquarters and manufacturing facility is located on a 15-acre site in Miami-Dade County, 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, 7.2 acres of the site and two approximately 40,000 square foot buildings located on this portion of the site, which we use for manufacturing, engineering, administrative and warehousing purposes. 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 and property at any time during the term of the lease for Aventis book value ($1.2 million at December 31, 2005). Aventis may terminate the lease prior to the expiration of its term upon termination or expiration of our 1992 license agreement with Aventis. The facility has been certified by the DEA to manufacture products containing controlled substances.

We lease approximately 15,700 square feet of office space in a neighboring facility for certain marketing and administrative functions and an additional 73,000 square feet of industrial space for warehousing which, depending on need, may also be used for manufacturing new products. Our site includes 5 acres of vacant land that we own 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 and Daytrana.

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

Item 3. Legal Proceedings.

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual plaintiff in Superior Court of New Jersey Law Division, Atlantic County in which the plaintiff claims personal injury allegedly arising from the use of HT products, including Vivelle®. The plaintiff claims compensatory, punitive and other damages in an unspecified amount. We do not expect any activity in this case in the near future, as the court has indicated that it intends to stay proceedings in all its pending and future HT cases except for cases where Wyeth Pharmaceuticals and its affiliates and Pfizer, Inc. are the defendants.

Novartis has advised us that Novartis has been named as a defendant in at least 16 additional lawsuits that include approximately 21 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 our Vivelle-Dot, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the one referenced above. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the

Table of Contents

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.

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, 2005.

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, 2006. 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 63, has been Vice President Clinical Development & Chief Medical Officer of Noven since September 2003. From March 2002 to October 2002, Dr. Abrao served as the Vice President, Regulatory Affairs and Drug Safety of Berlex Laboratories, Inc. 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 45, has been Vice President & Chief Financial Officer of Noven since May 2003. From August 2000 to January 2001, she served as Treasurer and Executive Director of Finance of Noven, and from January 2001 to May 2003 she served as Vice President Finance & Treasurer of Noven. 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 40, has been with Noven since November 1998 and, since May 2005, has served as Senior Vice President Strategic Alliances. From January 2001 to September 2001, he served as Noven s Vice President, General Counsel & Corporate Secretary, and from September 2001 to May 2005, he served as Noven s 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 53, 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.

Table of Contents

Juan A. Mantelle. Mr. Mantelle, age 47, has been with Noven since March 1990 and, since June 2000, has served as Vice President & Chief Technical Officer. From 1986 to 1990, he served Paco Research Corp. as Manager Product Development. From 1983 to 1986, he served Key Pharmaceuticals, Inc. as Senior Research Engineer.

Robert C. Strauss. Mr. Strauss, age 64, 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. In 1997, he served as President and Chief Operating Officer and as a Director of IVAX Corporation. From 1983 to 1997, he served in various executive positions with Cordis Corporation, most recently as its Chairman of the Board, President and Chief Executive Officer.

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, 2006, we had 264 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
Fourth Quarter, 2005	$ 16.38	$ 10.44
Third Quarter, 2005	18.23	12.14
Second Quarter, 2005	18.34	15.58
First Quarter, 2005	19.20	14.80
Fourth Quarter, 2004	$ 24.50	$ 14.62
Third Quarter, 2004	22.23	17.76
Second Quarter, 2004	23.65	16.75
First Quarter, 2004	25.96	15.05

Table of Contents

The following table provides information with respect to our stock repurchases during the fourth quarter of 2005:

	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, 2005 to October 31, 2005				$23,711,040
November 1, 2005 to November 30, 2005				$23,711,040
December 1, 2005 to December 31, 2005				$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.

Table of Contents

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,				
	2005	2004	2003	2002	2001
Statement of Operations Data:					
Net Revenues:					
Product revenue	$ 40,451	$ 36,871	$ 37,116	$ 50,199	$ 42,047
Contract and license revenue[1]	12,081	9,020	6,050	5,173	3,900
Total net revenues	52,532	45,891	43,166	55,372	45,947
Expenses:					
Cost of products sold[1, 2]	34,047	20,514	19,845	23,297	20,609
Research and development[2]	13,215	9,498	7,719	11,310	10,740
Marketing, general and administrative	16,915	17,271	15,858	14,257	11,554
Total expenses	64,177	47,283	43,422	48,864	42,903
(Loss) income from operations	(11,645)	(1,392)	(256)	6,508	3,044
Equity in earnings of Novogyne	24,655	17,641	17,094	14,368	14,013
Interest income, net	2,242	999	659	822	1,770
Income before income taxes	15,252	17,248	17,497	21,698	18,827
Income tax expense	5,280	6,024	6,301	7,819	6,736
Net income	$ 9,972	$ 11,224	$ 11,196	$ 13,879	$ 12,091
Basic earnings per share	$ 0.42	$ 0.48	$ 0.50	$ 0.62	$ 0.54
Diluted earnings per share	$ 0.42	$ 0.46	$ 0.49	$ 0.60	$ 0.51
Balance Sheet Data:					
Cash and cash equivalents	$ 66,964	$ 93,958	$ 83,381	$ 58,684	$ 49,389
Short-term investments	17,900				

Total assets	185,910	201,975	170,984	138,502	137,028
Capital lease obligation	121	235		5	13
Deferred license revenue	23,655	39,085	50,005	29,445	32,758
Stockholders equity	140,621	129,039	108,823	96,741	81,898

[1] Due to the FDA s determination that our fentanyl ANDA was not approvable, Noven and Endo agreed in December 2005 to terminate the fentanyl portion of the license agreement, as well as the fentanyl supply agreement between the parties, resulting in Noven earning the remaining $5.7 million of previously deferred license revenue, which was recognized in the fourth quarter of 2005. In addition, cost of products sold in 2005 included $9.9 million in charges relating to the write-off and associated destruction charges of fentanyl inventories.

[2] Cost of products sold has been revised for all years to include certain amounts previously included in research and development expenses.

Table of Contents

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 executive summary of our 2005 results of operations;

An overview of Noven and our Novogyne joint venture;

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

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

An outlook that includes our current financial guidance for 2006;

A discussion of how we apply our critical accounting estimates; and

A discussion of recently-issued accounting standards.

This discussion should be read in conjunction with Noven and Novogyne s 2005 financial statements and the related notes thereto included in this Form 10-K.

Executive Summary

The highlights of our results in 2005 included improvement in product sales of our HT patches, strong performance at our Novogyne joint venture, and progress made toward the regulatory approval of Daytrana , including the receipt of an approvable letter from the FDA and the commencement of Daytrana inventory production in December 2005. In February 2006, we provided the FDA with a resubmission to the Daytrana NDA intended to address the issues presented in the approvable letter. In March 2006, the FDA advised us that our resubmission was complete and that April 9, 2006 had been established as the user fee goal date for the FDA to complete its review of the resubmission.

The most significant negative development during 2005 was the FDA s determination that our fentanyl ANDA was not approvable. As a result of this determination, we wrote off the fentanyl inventories manufactured while the ANDA was pending at the FDA, resulting in an aggregate $9.9 million in charges to our cost of products sold in the second half of 2005. We also agreed in December 2005 to terminate those aspects of our collaboration with Endo that related to fentanyl, resulting in the recognition of $5.7 million of fentanyl deferred license revenues. The net effect of the fentanyl inventory charges and the recognition of fentanyl deferred license revenues was to reduce our 2005 income before income taxes by approximately $4.2 million.

Noven s net revenues for the year ended December 31, 2005 were $52.5 million, an increase of 14% compared to the prior year. Product revenues increased 10% to $40.5 million. Contract and license revenues increase 34% to $12.1 million, largely due to the recognition of the fentanyl deferred license revenues referenced above. Novogyne s profit contribution to Noven in 2005 was $24.7 million, a 40% increase compared to the prior year. Including the fentanyl inventory write-off charges and the recognition of fentanyl deferred license revenues, diluted earnings per share for 2005 was $0.42 compared to $0.46 in 2004.

At Novogyne, net revenues increased 15% to $121.6 million and net income increased 37% to $57.8 million. Vivelle-Dot net sales exceeded $100 million for the first time, and Vivelle-Dot total prescriptions increased 11% compared to 2004. Driven by the growth of prescriptions for

Table of Contents

Vivelle-Dot total prescriptions for Novogyne s products, taken as a whole, increased 4% in 2005 compared to the prior year.

The foregoing Executive Summary is qualified in its entirety by the more detailed discussion and analysis of our financial condition and results of operations appearing in this Item 7 as well as Noven s and Novogyne s 2005 financial statements and the related notes included in this Form 10-K.

Overview of Noven and our Novogyne Joint Venture

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 largely on Novogyne and its marketing of our three principal HT products Vivelle-Dot Vivelle® 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 the remaining 51% equity interest. Under the terms of the joint venture agreements, we manufacture and supply Vivelle-Dot, Vivelle® and CombiPatch® to Novogyne, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of ET products. Novartis distributes Vivelle-Dot Vivelle® and CombiPatch® and provides certain other services to Novogyne, including contracting with the managed care sector, and all regulatory, accounting and legal services.

Novartis is entitled to an annual $6.1 million preferred return from Novogyne, 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 $24.7 million, $17.6 million and $17.1 million in 2005, 2004 and 2003, 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 to distribute our equity earnings. Accordingly, the amount of cash that we receive from Novogyne in any period may not be the same as the amount of income we recognize from Novogyne for that period. In 2005, 2004 and 2003, we received $26.2 million, $18.1 million and $21.7 million, respectively, 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.

Table of Contents

Comparing the second quarter of 2002 (the quarter immediately preceding the publication of initial data from the WHI study) to the fourth quarter of 2005, total prescriptions dispensed in the HT market in the United States decreased by 53.3%. For the same period, aggregate prescriptions for Noven s United States HT products decreased 9.2%. The estrogen segment of the HT market in the United States declined 48.7%, while our Vivelle® line of products increased 3.1%. Vivelle-Dot, which represented 85% of our total United States prescriptions in the fourth quarter of 2005, increased 29.9% from the second quarter of 2002 to the fourth quarter of 2005. We believe Vivelle-Dot patch prescriptions have benefited from patient conversions from the original Vivelle® product, which represented approximately 4% of our total United States prescriptions in the fourth quarter of 2005. Manufacturing of Vivelle® is expected to be discontinued by the end of 2006.

United States prescriptions for our CombiPatch® product (which represented approximately 11% of our total United States prescriptions in the fourth quarter of 2005) declined 53.9% from the second quarter of 2002 to the fourth quarter of 2005, while prescriptions for the total United States market for fixed combination hormone therapy decreased 71.0%. 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 Estimates Investment in Novogyne.

Certain Items that May Affect Historical or Future Comparability

Stock Options

As a result of recent changes in accounting principles generally accepted in the United States (GAAP), in 2006 and thereafter, our Statements of Operations will include significant expenses associated with equity compensation that we were not required to include in 2005 and prior periods. Effective January 1, 2006, we adopted Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123 (Revised 2004) Accounting for Stock-Based Compensation (SFAS No. 123), Share-Based Payment (SFAS 123(R)), which requires compensation expense associated with equity awards to be recognized in our Statements of Operations, rather than as historically presented as a pro forma footnote disclosure in our financial statements. In order to reduce the future compensation expense that we would otherwise recognize in our Statement of Operations following adoption of SFAS123(R), the Compensation and Stock Option Committee of our Board of Directors approved, during 2005, the acceleration of vesting of certain stock options under the Noven 1999 Long-Term Incentive Plan. As a result of this action, options to purchase approximately 1.1 million shares of Noven s common stock became immediately exercisable, including options held by Noven s executive officers to purchase approximately 455,000 shares. We recorded an immaterial charge to compensation expense during 2005 due to the acceleration of a nominal amount of in-the-money options. As a result of the acceleration, during 2005, approximately $10.1 million of future compensation expense, net of applicable income taxes, was eliminated from our Statements of Operations and included in the pro-forma footnote disclosure in our financial statements for 2005. Including this amount, our total compensation expense presented in footnote disclosure, net of applicable income taxes, was $14.1 million, $5.8 million and $3.6 million for 2005, 2004 and 2003, respectively. At December 31, 2005, the unamortized compensation expense that we expect to

Table of Contents

record in future years related to outstanding unvested options, as determined in accordance with SFAS 123(R) is approximately $8.3 million before the effect of income taxes, of which $3.1 million, $2.7 million, $1.8 million and $0.7 million is expected to be incurred in 2006, 2007, 2008 and 2009, respectively. We will also incur additional expense in future years related to new equity awards that may be granted in the future that cannot yet be quantified.

Shire

We have developed a transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder with the proposed brand name Daytrana. Global rights to the developmental product have been licensed to Shire for payments of up to $150.0 million, including $25.0 million paid at closing of the license transaction in the second quarter of 2003. In 2004 and 2005, Shire conducted additional clinical trials that were intended to address clinical issues raised in the not approvable letter that we received from the FDA in April 2003 relating to our NDA for Daytrana. In June 2005, we submitted an amendment to the NDA that included these new trial results, and in December 2005, we received an approvable letter from the FDA for Daytrana. The approvable letter contains proposed revisions to labeling, as well as requests for data clarification, post-marketing surveillance, and post-marketing studies. In February 2006, we provided the FDA with a resubmission to the Daytrana NDA intended to address the issues presented in the approvable letter. In March 2006, the FDA advised us that our resubmission was complete and that April 9, 2006 had been established as the user fee goal date for the FDA to complete its review of the resubmission. In February 2006, Shire and Noven agreed to reduce the amount Shire may require Noven to pay to repurchase the product rights to Daytrana under certain circumstances, from $5.0 million to $4.0 million.

Beginning in the fourth quarter of 2003, we have been recording reimbursements to Shire for Shire s direct costs and certain direct incremental costs incurred by Noven as requested by Shire in pursuit of Daytrana regulatory approval. These reimbursements have been recorded as a reduction of a portion of the $21.0 million that is nonrefundable deferred license revenue previously received from Shire ($25.0 million license payment less the $4.0 million repurchase right). Because Shire had made a significant investment related to licensing Daytrana, Shire wanted to manage the development program in order to advance Daytrana toward approval. Therefore, we effectively agreed to reimburse Shire a portion of Shire s non-refundable license payment for certain costs Shire incurred directly in pursuit of approval. Furthermore, due to the fact Shire requested that we incur certain direct incremental costs in pursuit of approval, we treated such costs as reimbursements as well. Such reimbursements and direct incremental costs did not impact Noven s research and development expenses in 2005, 2004 or 2003, although the reimbursements or amounts reimbursable to Shire reduced and will reduce Noven s cash position and also reduced and will continue to reduce the amount of deferred revenues that Noven may recognize in future periods. As of December 31, 2005, $4.8 million remained in deferred license revenue, of which $4.0 million is subject to Shire s repurchase right and is therefore considered refundable. We believe that future reimbursements to Shire will not exceed the $0.8 million, which is the remaining amount of non-refundable deferred license revenue.

As described in more detail below under Critical Accounting Estimates Inventories - Pre-Launch Inventories , as of December 31, 2005 our inventories include $2.4 million of Daytrana pre-launch inventories. If Daytrana is not ultimately approved or this inventory is ultimately not commercially saleable, Shire would bear the full cost of any inventory write-off.

Table of Contents

Endo

In July 2003, we submitted an ANDA to the FDA seeking approval to market a generic fentanyl patch. In the first quarter of 2004, we entered into an agreement with Endo granting Endo the exclusive right to market our fentanyl patch in the United States. We received an up-front payment of $8.0 million from Endo, of which $6.5 million was allocated to license revenue for the fentanyl patch and the remaining $1.5 million was allocated based on fair value to fund feasibility studies that seek to determine whether certain compounds identified by the parties can be delivered through our transdermal patch technology. Our agreement with Endo provides that Endo would fund and manage clinical development of those compounds proceeding into clinical trials.

In July 2005, the FDA issued a public advisory that it is investigating reports of death and other serious side effects from overdoses involving both the branded and generic fentanyl patches. In September 2005, the FDA advised us that it did not expect to approve our ANDA and was consequently ceasing its review of our ANDA, based on the FDA s assessment of potential safety concerns related to the higher drug content in our generic product versus the branded product. The FDA subsequently confirmed in writing that our fentanyl ANDA was not approvable.

We had agreed with Endo that we would manufacture initial launch quantities of our fentanyl patch prior to receipt of final regulatory approval from the FDA and that the parties would share the cost of any non-saleable fentanyl inventories in accordance with an agreed-upon formula. As a result of the FDA s decision to cease review of our ANDA, we deemed the entire $14.0 million of fentanyl patch inventories to be non-saleable and recorded a $9.5 million charge to our cost of products sold in the third quarter of 2005. This charge represented the portion of the cost of the existing fentanyl inventories and purchasing commitments for raw materials allocable to us under the contractual formula. Endo was responsible for the remaining $4.5 million of the fentanyl patch production costs, which they paid us in the fourth quarter of 2005, less the $2.6 million that we owed Endo for fentanyl raw materials. In addition, we incurred approximately $0.4 million in costs associated with disposal and destruction of our fentanyl inventories in the fourth quarter of 2005, which was charged to costs of products sold in that quarter. See Critical Accounting Estimates Inventories Pre-Launch Inventories for information regarding our estimates and judgments related to pre-launch inventories. Due to the FDA s determination that our fentanyl ANDA was not approvable, Noven and Endo agreed in December 2005 to terminate the fentanyl portion of the license agreement as well as the fentanyl supply agreement between the parties. As a result of the termination and the fact that we have no obligation to Endo and no continuing involvement related to the fentanyl license agreement as of December 31, 2005, we earned the remaining $5.7 million of previously deferred license revenue and recognized it as license revenue in the fourth quarter of 2005.

We are currently evaluating the feasibility of reformulating the fentanyl patch to address the FDA s concerns; however, no assurance can be given that we will be able to successfully reformulate the patch, that a reformulated patch would be approved by the FDA or that we would be able to successfully market a reformulated patch.

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.

Table of Contents

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 2003 net revenues by $1.4 million and $6.5 million, 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 was to increase Noven s income before income taxes by $2.2 million in 2004. There are no remaining allowances at Noven or Novogyne related to the 2003 recall.

As a result of the 2003 stability failures, we initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production. 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. The recall of these lots in the first quarter of 2005 did not have a material impact on Noven s or Novogyne s results of operations because an immaterial number of patches from these lots remained in distribution. Noven s marketing, general and administrative expense in 2004 included an allowance of $0.3 million for estimated costs related to these recalls, which allowance was reduced by $0.2 million during 2005, based on the final close out of the recall. A joint Noven and Novartis task force is working to identify the definitive root cause of the Vivelle-Dot stability failures. Based on testing and analysis to date, we believe that the probable cause of the Vivelle-Dot stability failures relates to certain patch backing material that we obtained from a raw material supplier. If the root cause determination or additional testing indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. We continue to manufacture and ship Vivelle-Dot to Novogyne.

In 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 recalled the affected lot. The recall of this lot did not have a material impact on Noven s and Novogyne s financial results in either 2004 or 2005. We continue to manufacture and ship CombiPatch® to Novogyne.

In the fourth quarter of 2005, special stability protocols put in place after the October 2004 CombiPatch® stability failure indicated that certain lots of Estalis® (a product substantially similar to CombiPatch® and manufactured for sale outside the United States) did not maintain required specifications throughout the product s shelf-life due to the formation of crystals, resulting in the recall by Novartis Pharma of a total of three commercial lots of Estalis®. We are investigating the cause of the stability failure. The recall of these lots did not have a material impact on Noven s financial statements in 2005. We continue to manufacture and ship Estalis® to Novartis Pharma.

We continue to maintain stability testing related to the foregoing production issues. If our testing indicates that additional lots of our products or lots of products that have not previously experienced failures do not meet specifications, there could be additional recalls. Although Noven and Novartis work together in assessing production issues related to these products, the decision to recall product resides with Novartis as the holder of the NDAs for these products and is not within

Table of Contents

our control. If our estimates concerning product returns associated with the recall are incorrect, or if our continued testing indicates that additional lots are 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. Among other things, any CombiPatch® recalls could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights.

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.

Table of Contents

Results of Operations

Revenues:

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

	2005	% Change	2004	% Change	2003
Product revenues Novogyne:					
Product sales	$ 19,910	6%	$ 18,798	18%	$ 15,932
Royalties	6,444	24%	5,204	5%	4,978
	26,354	10%	24,002	15%	20,910
Product revenues third parties:					
Product sales	13,779	12%	12,327	(23%)	16,078
Royalties	318	(41%)	542	323%	128
	14,097	10%	12,869	(21%)	16,206
Total product revenues	40,451	10%	36,871	(1%)	37,116
Contract and license revenues:					
Contract	2,528	(50%)	5,021	148%	2,024
License	9,553	139%	3,999	(1%)	4,026
	12,081	34%	9,020	49%	6,050
Net revenues	$ 52,532	14%	$ 45,891	6%	$ 43,166

Net Revenues

As described in more detail below, the 14% increase in 2005 net revenues as compared to 2004 was attributable to an increase in license revenues related to Endo, an aggregate increase in sales for our U.S. and international products and an increase in royalties as a result of Novogyne s higher sales of Vivelle-Dot These increases were partially offset by a decline in contract revenues.

As described in more detail below, the 6% increase in 2004 net revenues as compared to 2003 was primarily attributable to higher contract revenue due to the earning of certain product development milestones and an increase of product sales in the United States to Novogyne. In addition, net revenues in 2004 also benefited from a reduction in allowances for returns. These increases were partially offset by a decline in sales of our international products.

Product Revenues Novogyne

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

Table of Contents

The $2.4 million increase in revenues from Novogyne for 2005 as compared to 2004 primarily related to a $1.6 million increase in unit sales of Vivelle-Dot and a $1.2 million increase in royalties. This increase was offset by a $0.6 million decline in unit sales of Estradot® for Canada. The increase in Vivelle-Dot product sales and royalties was attributable to higher sales at Novogyne due to increased prescription trends. The decline in unit sales of Estradot® was primarily attributable to stocking orders in 2004 related to a planned transition from Vivelle® to Estradot® in Canada. Price was not a factor contributing to the overall increase.

The $3.1 million increase in revenues from Novogyne for 2004 as compared to 2003 primarily related 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 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 were offset by a $0.8 million decline 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.

Product Revenues Third Parties

Product revenues third parties consists primarily of sales of Estradot®, Estalis® and Menorest to Novartis Pharma at a price based on a percentage of Novartis Pharma 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 $1.2 million increase in product revenues from third parties for 2005 as compared to 2004 primarily related to $0.5 million increase in unit sales and a $0.7 million increase related to pricing. The increase in unit sales was mostly attributable to $0.6 million in higher sales of Estalis®. We believe this increase was attributable to the timing of orders due to the re-stocking of inventory in launched countries and not to an increase in underlying demand. The $0.7 million increase in revenue related to pricing was primarily due to the recognition of a higher price adjustment payment received from Novartis Pharma in 2005 compared to 2004. Noven records such price adjustment payments from time to time upon Novartis Pharma s determination that its actual sales price of our product entitles us to receive amounts in excess of the minimum transfer price at which we initially sell the product to Novartis Pharma.

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 indicated in 2004 that it had 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, which was mainly attributable to the collection in 2004 of royalties associated with 2001 through 2003 sales of Estradot® in Canada that was previously being negotiated with Novartis Pharma. The higher sales of Estradot® is related to an increase of $1.1 million in price adjustment

Table of Contents

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.

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 non-refundable up-front, milestone and similar payments under license agreements.

The $2.5 million decline in contract revenues for 2005 as compared to 2004 was primarily related to our recognition in 2004 of $4.4 million in product development milestones under our collaboration with P&G Pharmaceuticals that did not recur in 2005. This decline was partially offset by $1.9 million in contract revenues related to work performed in 2005 on development contracts. The $5.6 million increase in license revenue is mostly attributable to the recognition of the remaining deferred revenue balance related to our fentanyl agreement with Endo.

The increase in contract revenues of $3.0 million for 2004 as compared to 2003 was primarily attributable to $4.4 million earned in 2004 in connection with our P&G Pharmaceuticals collaboration. License revenues were consistent in 2004 and 2003.

Gross Margin:

The following section presents Noven s gross margin on an overall basis and also discusses gross margin for: (i) Novogyne-related product revenues and (ii) third party-related product revenues. Noven s overall gross margin (and that related to third parties) significantly declined in 2005 as a result of the write-off of $9.9 million of fentanyl pre-launch inventories and associated destruction costs. The following section includes a discussion of gross margins that excludes the effect of these fentanyl-related charges in 2005 as well as the effect of our deferral of profits on products we sell to Novogyne. We believe such non-GAAP presentation is useful to investors in order to meaningfully evaluate Noven s ongoing, underlying business and compare Noven s financial results in 2005 to those in the prior year. For the same reasons, management uses these non-GAAP financial measures to evaluate Noven s ongoing, underlying business. These measures should not be considered alternatives to measures computed in accordance with GAAP, nor should they be considered indicators of our overall financial performance.

Table of Contents

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

	2005	2004	2003
Gross Margin Total:			
Product revenues	$ 40,451	$ 36,871	$ 37,116
Cost of products sold	34,047	20,514	19,845
Gross profit (product revenues less cost of products sold)	6,404	16,357	17,271
Gross margin (gross profit as a percentage of product revenues)	16%	44%	47%
Pre-launch inventory write-off and associated destruction charges	9,917		
Changes in deferred profit on sales of product to Novogyne	284	(254)	(1,140)
Gross profit excluding pre-launch inventory write-off and associated destruction charges and impact of deferred profit	16,605	16,103	16,131
Gross margin excluding pre-launch inventory write-off and associated destruction charges and impact of deferred profit	41%	44%	43%

As noted above, our overall gross margin was significantly and adversely affected in 2005 by the increased cost of products sold resulting from the write-off of the fentanyl inventory and related destruction charges. Excluding the fentanyl-related charges and the changes in deferred profit, our gross margin was 3% lower in 2005. This decrease resulted primarily from the increased costs for the expansion of manufacturing and operational capacity in anticipation of new product launches as well as increased personnel and other resources dedicated to quality control and quality assurance in our HT product line. Our unadjusted overall gross margin was 3% lower in 2004 than in 2003. This decrease resulted primarily from the effect that our deferral of profits on products we sell to Novogyne has on the amount of our gross margin from period to period, as is discussed in the following section. Excluding the impact of deferred profit, the 1% increase in overall gross margin in 2004 as compared to 2003 is mainly attributable to the impact of the reductions in product recall reserves as discussed in more detail below.

Table of Contents

Gross Margin Sales to Novogyne

	2005	2004	2003
Gross Margin Novogyne:			
Product revenues	$ 26,354	$ 24,002	$ 20,910
Cost of products sold	13,547	11,413	8,753
Gross profit (product revenues less cost of products sold)	12,807	12,589	12,157
Gross margin (gross profit as a percentage of product revenues)	49%	52%	58%
Changes in deferred profit on sales of product to Novogyne	284	(254)	(1,140)
Gross profit excluding changes in deferred profit on sales of product to Novogyne	13,091	12,335	11,017
Gross margin excluding impact of deferred profit	50%	51%	53%

Noven s cost of products sold is affected by deferred profit 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 reflect less deferred 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 these fluctuations, we have included our gross margin related to Novogyne excluding the changes in deferred profit on sales of product to Novogyne. Noven s management believes that this presentation, for the reasons described above, is more meaningful and useful to an understanding of Noven s underlying gross margin related to Novogyne.

The decrease in gross margin related to Novogyne, excluding the impact of deferred profit over the last two years, is primarily related to the increased personnel and other resources in our HT business as described above. In addition, gross margin related to Novogyne in 2005 as compared to 2004 was negatively impacted by the $0.6 million reductions in 2004 of allowances for returns established in 2003. The decrease in gross margin related to Novogyne in 2004 as compared to 2003, was partially offset by the $2.0 million net effect of the $0.6 million reductions in 2004 of allowances for returns of $1.4 million established in 2003.

Table of Contents

Gross Margin Sales to third parties

	2005	2004	2003
Gross Margin Third Parties:			
Product revenues	$ 14,097	$ 12,869	$ 16,206
Cost of products sold	20,500	9,101	11,092
Gross profit (product revenues less cost of products sold)	(6,403)	3,768	5,114
Gross margin (gross profit as a percentage of product revenues)	(45%)	29%	32%
Pre-launch inventory write-off and associated destruction charges	9,917		
Gross profit excluding pre-launch inventory write-off and associated destruction charges	3,514	3,768	5,114
Gross margin excluding pre-launch inventory write-off	25%	29%	32%

As discussed above, our 2005 gross margin was adversely affected by the write-off and associated destruction charges related to our fentanyl inventories. The decline in gross margin related to third parties, excluding the impact of the fentanyl write-off and associated destruction charges, over the last two years was primarily related to the expansion of manufacturing and operational capacity in anticipation of new product launches, which are expensed as incurred, as well as an increase in personnel and other resources in our HT business as described above. This decrease was partially offset in both 2005 and 2004 in comparison to the respective prior year due to increases of $0.7 million in 2005 and $1.1 million in 2004 in price adjustment payments. Furthermore, gross margin related to third parties in 2004 further benefited from a $0.4 million increase in product royalties, due to the collection and recognition in 2004 of royalties associated with 2001 through 2003 sales of Estradot® in Canada.

Table of Contents

Operating Expenses:

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

	2005	% Change	2004	% Change	2003
Research and development	$13,215	39%	$ 9,498	23%	$ 7,719
Marketing, general and administrative	16,915	(2%)	17,271	9%	15,858

Research and Development

Research and development expense includes costs associated with, among other things, product formulation, pre-clinical testing, clinical studies, regulatory and medical affairs, production of product for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel associated with each of these functions.

The $3.7 million increase in 2005 as compared to 2004 was primarily attributable to a $2.8 million increase in development engineering related to our methylphenidate and fentanyl patches, a $0.4 million increase in clinical studies and a $0.3 million increase in personnel costs.

The $1.8 million increase in 2004 as compared to 2003 was primarily attributable to a $1.5 million increase in development engineering related to our fentanyl patch, a $1.2 million increase in pre-clinical testing, and a $0.7 million increase in personnel costs. This increase was partially offset by a $1.8 million reduction in clinical studies related to our methylphenidate patch. Beginning in the fourth quarter of 2003, Shire managed the development program in order to advance Daytrana toward approval as discussed above.

Marketing, General and Administrative

The $0.4 million decline in 2005 as compared to 2004 was primarily attributable to a $0.7 million reduction in professional fees related to compliance with the Sarbanes-Oxley Act of 2002 and other regulatory requirements. In addition, during 2005, we reduced our allowance for costs related to product recalls by $0.2 million, which were originally established with a $0.3 million charge during 2004. This accounts for $0.5 million of the decrease in marketing, general and administrative expenses for 2005 as compared to 2004. Also, during 2004, $0.3 million was charged to marketing, general and administrative expenses related to the disposal of manufacturing equipment. The decline in expenses was partially offset by a $0.9 million increase in costs associated with expansion for anticipated new product launches, and a $0.4 million increase in consulting and professional fees, primarily for human resource related projects.

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 internal control requirements resulting from the Sarbanes-Oxley Act of 2002 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

Table of Contents

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.

Other Income and Expenses:

Interest Income

Interest income is summarized as follows (dollar amounts in thousands):

	2005	% Change	2004	% Change	2003
Interest income, net	$2,242	124%	$ 999	52%	$ 659

Interest income increased $1.2 million in 2005 as compared to 2004 and was primarily attributable to the investing of a portion of our cash into short-term investments that yielded higher interest income, which primarily consist of investment grade, asset backed, variable debt obligations and municipal auction rate securities as well as an increase in interest rates.

Interest income increased $0.3 million in 2004 as compared to 2003 and was primarily attributable to a higher average cash balance during 2004 in comparison to 2003 as well as an increase in interest rates.

Income Taxes

Our effective tax rate was 35%, 35% and 36% for 2005, 2004 and 2003, respectively. 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 $0.4 million reduction in accruals for outstanding Internal Revenue Service (IRS) audits due to the expectation of a more favorable outcome at that time.

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, 2005, we had a net deferred tax asset of $12.4 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

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 2005, 2004 and 2003 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.

Table of Contents

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

	2005	% Change	2004	% Change	2003
Gross revenues[1]	$ 136,901	10%	$ 124,791	4%	$ 120,282
Sales allowances	14,408	10%	13,154	17%	11,279
Sales returns allowances	936	(85%)	6,224	(21%)	7,926
Sales and returns allowances	15,344	(21%)	19,378	1%	19,205
Net revenues	121,557	15%	105,413	4%	101,077
Cost of sales[2]	28,696	3%	27,755	0%	27,664
Gross profit	92,861	20%	77,658	6%	73,413
Gross margin percentage	76%		74%		73%
Selling, general and administrative expenses	35,568	(0%)	35,624	16%	30,673
Income from operations	57,293	36%	42,034	(2%)	42,740
Interest income	461	141%	191	5%	182
Net income	$ 57,754	37%	$ 42,225	(2%)	$ 42,922
Noven s equity in earnings of Novogyne	$ 24,655	40%	$ 17,641	3%	$ 17,094

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

[2] Included in Novogyne s costs of sales is the amortization of the marketing rights Novogyne acquired for CombiPatch®, which in prior periods was listed as a separate operating expense in Novogyne s statement of operations.

Novogyne Revenues

Novogyne s gross revenues increased $12.1 million for 2005 as compared to 2004, primarily due to a $15.6 million increase in sales of Vivelle-Dot, partially offset by a $1.5 million decline in sales of Vivelle®, a $1.3 million decline in unit sales of Estradot® to an affiliate of Novartis Pharma in Canada (Novartis Canada), and a $0.7 million decline in sales of CombiPatch®. Approximately $8.4 million of the Vivelle-Dot increase was due to increased unit sales based on increased trade demand, while the remaining $7.2 million increase related to price increases. The decline in Vivelle®, our first generation estrogen patch, was mostly attributable to a decline in unit sales due to product maturity. The decline in sales of Estradot® to Novartis Canada is primarily attributable to the timing of orders, as 2004 sales benefited from Novartis Canada stocking inventory as they transitioned from Vivelle® to Estradot®. The lower sales of CombiPatch® were due to a continuing decline in the market for combination therapies as well as the impact of a competitive product.

Table of Contents

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 Novartis Canada, partially offset by a $2.2 million decrease in unit sales of Vivelle® and a $4.6 million decrease in volume sales of CombiPatch®. We believe the increase in Estradot® sales to Novartis Canada was due to Novartis Canada stocking inventory as they transitioned from Vivelle® to Estradot®. 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 trade demand. The decline in volume sales of Vivelle® is primarily attributable to Vivelle® being in a declining trend due to product maturity. Manufacturing of Vivelle® is expected to be discontinued by the end of 2006. The lower volume sales of CombiPatch® 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.

The following table describes Novogyne s sales and returns allowances for the years ended December 31, 2005, 2004 and 2003 (dollar amounts in thousands):

	2005	% of gross revenues	2004	% of gross revenues	2003	% of gross revenues
Gross revenues	$ 136,901		$ 124,791		$ 120,282	
Managed health care rebates	8,018	6%	7,898	6%	6,575	5%
Cash discounts	2,690	2%	2,425	2%	2,363	2%
Medicaid, Medicare & State program rebates and credits including prescription drug saving cards	938	1%	1,341	1%	950	1%
Chargebacks, including hospital chargebacks	970	1%	861	1%	838	1%
Other discounts	1,792	1%	629	1%	553	0%
Sales allowances	14,408	11%	13,154	11%	11,279	9%
Sales returns allowances	936	1%	6,224	5%	7,926	7%
Sales and returns allowances	15,344	11%	19,378	16%	19,205	16%
Net revenues	$ 121,557		$ 105,413		$ 101,077	

Table of Contents

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, 2005, 2004 and 2003 was as follows (amounts in thousands):

	2005	2004	2003
Current year provisions for returns of expiring product	$ 3,384	$ 8,342	$ 3,798
Adjustment to prior year provisions for returns of expiring product	(2,385)	1,227	(2,372)
(Benefits) provisions for returns for product recalls	(63)	(3,345)	6,500
Sales returns allowances	$ 936	$ 6,224	$ 7,926
Actual returns for expiring product	(3,897)	(8,675)	(5,931)
Actual returns for product recalls	(40)	(2,620)	(535)
Actual returns during the year ended	$ (3,937)	$ (11,295)	$ (6,466)

The decrease in allowances for returns of expiring product for 2005 as compared to 2004 was primarily related to lower than expected returns as a result of a decline in actual returns of Vivelle® and Vivelle-Dot in 2005, offset by increased sales of Vivelle-Dot. As a result of this analysis, allowances related to prior years were reduced by $2.4 million.

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®. As a result of this analysis, allowances related to prior years were increased by $1.2 million. As a result of the 2003 product recalls, Novogyne recorded a $6.5 million estimated returns reserve related to the announced recall as of December 31, 2004. During the latter part of 2003 and through December 31, 2004, $3.2 million of actual returns associated with the recall were processed. The remaining recall reserve of $3.3 million was reversed to income in 2004, as the FDA closed out the recall.

Novogyne Gross Margin

The 2% gross margin increase in 2005 as compared to 2004 was primarily related to lower sales returns allowances attributable to lower than expected returns as described above as well as higher sales of Vivelle-Dot, which has a higher gross margin than other products sold by Novogyne, and lower sales of Estradot®, which has a lower gross margin than other products sold by Novogyne. Gross margin percentage in 2004 was comparable to that in 2003.

Novogyne Selling, General and Administrative

Novogyne s selling, general and administrative expenses declined $0.1 million for 2005 as compared to 2004, due to a $0.9 million decline in sample expenses primarily attributable to the timing of sample orders by Novogyne, a $0.8 million decline in advertising and promotion expenses, and a $0.4 million decline in HT litigation expense. These declines were partially offset by a $0.6 million increase in sales force expenses, and a $0.3 million increase in professional services costs. In addition, 2004 benefited from a $0.9 million reduction in expenses associated with the co-promotion of one of Novartis products.

Table of Contents

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

Liquidity and Capital Resources:

As of December 31, 2005 and December 31, 2004, we had the following (amounts in thousands):

	December 31, 2005	December 31, 2004
Cash and cash equivalents	$ 66,964	$ 93,958
Short-term investments	17,900	
Working capital	91,122	97,349

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

	2005	2004	2003
Cash flows:			
Operating activities	$ 3,885	$11,869	$29,104
Investing activities	(32,055)	(7,115)	(4,722)
Financing activities	1,176	5,823	315

Operating Activities:

Net cash provided by operating activities in 2005 primarily resulted from the receipt of $26.2 million in distributions from Novogyne, partially offset by the timing of certain payments, including reimbursement payments of $10.3 million to Shire related to the development of Daytrana, $3.2 million for purchases of fentanyl, $3.7 million for incentive compensation and related liabilities, and $2.5 million related to insurance.

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

Table of Contents

capital due to the timing and amount of product shipments, payment of director s and officer s insurance premiums and payment of income taxes.

Investing Activities:

Net cash used in investing activities in 2005 was primarily attributable to $17.9 million in net purchases of short-term investments, as well as the purchase of $13.7 million in fixed assets to expand production capacity for future products. Beginning in the first quarter of 2005, Noven invested a portion of its cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of Statement of Financial Accounting Standards (SFAS) No. 115 Accounting for Certain Investments in Debt and Equity Securities .

Net cash used in investing activities in 2004 and 2003 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 2005 and 2004 was attributable to $1.3 million and $5.9 million, respectively, 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 by Noven of 105,000 shares of common stock.

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, 2005, 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, license fees and distributions 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.

As a result of the FDA s decision to cease review of our ANDA for our fentanyl patch, we deemed the entire $14.0 million of pre-launch fentanyl patch inventories, as of September 30, 2005, to be non-saleable and recorded a $9.5 million charge to our costs of products sold in 2005. This charge represents the portion of the cost of the existing fentanyl inventories and purchasing

Table of Contents

commitments for raw materials allocable to us under the contractual formula. Endo was responsible for the remaining $4.5 million of the fentanyl patch production costs, and paid us for their portion in the fourth quarter of 2005 less the $2.6 million we owed Endo for fentanyl raw materials. In addition, in the 2005 fourth quarter we incurred $0.4 million in costs associated with disposal and destruction of our fentanyl inventories. Due to the FDA s determination that our fentanyl ANDA was not approvable, Noven and Endo agreed in December 2005 to terminate the fentanyl portion of the license agreement as well as the fentanyl supply agreement.

Capital expenditures were $14.6 million in 2005, of which $0.9 million represented landlord-funded leasehold improvements to a leased facility. We expect to continue to invest in capital expenditures during 2006 as we continue to expand our manufacturing and storage facilities for products under development, but we expect such expenditures to be significantly below 2005 levels. 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.

During 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 are using 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% 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 3% during the initial 10-year term. After the initial term, the rent will be 95% of the fair market rate of the leased space as determined under the Lease. We improved the leased space in order to prepare it for its intended use during 2005. The landlord was responsible for up to approximately $0.9 million of leasehold improvements, which were fully paid in 2005. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements were our responsibility. For accounting purposes, we are amortizing the 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. Leasehold improvements were recorded at cost and are being amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the initial 10-year lease term. Leasehold improvements to the leased space paid by the landlord were recorded by us as a deferred rent credit and are being 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 are 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

Table of Contents

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 Risk Factors.

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, 2005 (amounts are in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations[1]	$ 7,957	$ 843	$ 1,730	$ 1,726	$ 3,658
Capital Lease Obligation[2]	125	125			
Purchase Obligations[3]	16,020	15,621	399		
Total[4]	$ 24,102	$ 16,589	$ 2,129	$ 1,726	$ 3,658

[1] In the ordinary course of business, we enter into operating leases for machinery, equipment, warehouse and office space. In addition, as noted above, in 2005 we entered into an Industrial Long-Term Lease for approximately 73,000 square feet of storage space. Total rental expense for operating leases was $1.1 million, $0.5 million and $0.3 million for the years ended December 31, 2005, 2004 and 2003, respectively.

[2] During 2004 we entered into a capital lease obligation in the amount of $0.3 million for new equipment. The amount above includes the interest expense associated with this lease.

[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] Excludes $4.0 million that we may be required to pay to Shire if Shire exercises its right to require us to repurchase the product rights of our methylphenidate patch. See Development Collaborations Shire.

Table of Contents

Outlook

A summary of our current 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, among other things, that during 2006 there will not be any material:

transactions;

changes in Noven s or Novogyne s accounting or accounting principles (except as indicated below with respect to Noven s method of accounting for equity compensation) or any of the estimates or judgments underlying its critical accounting policies;

regulatory, technological or clinical study developments;

changes in the supply of, demand for, or distribution of our HT products (including any changes resulting from competitive HT products, product recalls, 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, and 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 above under the caption Risk Factors.

Equity Compensation Expense. Effective as of the first quarter of 2006, we adopted SFAS 123(R), Accounting for Stock Based Compensation. See Management s Discussion and Analysis of Financial Condition and Results of Operations New Accounting Standards. As a result, our Statements of Operations in 2006 and subsequent periods will include significant expenses associated with equity compensation that were not included in 2005 and prior periods. Based on the expense associated with equity compensation previously awarded, and our estimate of the expense associated with equity compensation that may be awarded in the course of 2006, we estimate that our total equity compensation expense for 2006 will be in the $4.0 million range. On our Statements of Operations, equity compensation expense will be allocated among the various expense categories in which the compensation of the equity award recipients has historically been recorded. As a result, certain expense categories (including cost of products sold, research and development, and marketing general and administrative) in future periods may reflect increases associated with the expensing of equity compensation. The specific financial guidance provided below does not reflect any increases resulting from the expensing of equity compensation in 2006.

Potential Daytrana Revenues. An amended NDA for Daytrana , our methylphenidate transdermal system, is currently pending at the FDA. Although we received an approvable letter for Daytrana in December 2005, we are unable to predict when or if the NDA will be approved. If the NDA is approved by the FDA, our agreement with Shire calls for us to receive an approval-related milestone payment of $50 million from Shire (the global licensee of the product) and may also earn additional milestone payments of up to $75 million depending on the level of Shire s commercial

Table of Contents

sales of the product. Approval and sales milestones will be deferred and recognized as Noven contract and license revenues on a quarterly basis through the first quarter of 2013, which is our best estimate of the end of the product life-cycle. Noven also expects to earn a profit on the ongoing manufacture and supply of finished product to Shire.

HT Product Revenues. Given customer orders and forecasts for our HT products and other factors, for full-year 2006 we forecast an aggregate increase in U.S. HT product revenues (led by sales of Vivelle-Dot) to approximately offset an expected aggregate decrease in international product revenues.

Increased Overhead. Over the past two years, we prepared our facilities and staffing for the production of fentanyl, Daytrana™ and other developmental products. Our results of operations and gross margins for future periods are expected to be adversely affected by these preparations and related continuing overhead expenses unless and until we are able to improve the utilization of these resources through the commercialization of additional products. During the same period, we increased personnel and other resources dedicated to quality control and quality assurance in our HT product line, which has contributed to an increase in the ongoing overhead expense associated with our HT business.

Research and Development. We expect our research and development expense in 2006 to be at least equal to full-year 2005 levels. We are working to formulate certain new transdermal products that, if successfully formulated, may enter human studies during 2006. These studies, if initiated, would be funded by Noven and would cause our research and development expense in 2006 to increase substantially over 2005 levels.

Marketing, General and Administrative Expense. For full-year 2006, we expect Noven s marketing, general and administrative expense in 2006 to increase in the 10% range over 2005 levels, reflecting in part anticipated increases in alliance management and information technology functions.

Novogyne. Based on current prescription trends and other factors, we expect that Novogyne s net revenues, net income and profit contribution to Noven to increase for full-year 2006 compared to 2005 levels.

Effective Tax Rate. We estimate that our effective tax rate for full-year 2006 will be in the 35%-37% range.

Capital Expenditures. We expect our capital expenditures for full-year 2006 to decrease significantly compared to 2005 levels, with 2006 spending weighted more heavily in the first half of the year.

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

Table of Contents

related to allowance for returns related to product recalls, accrued liabilities, income and other tax accruals, impairment of long-lived assets 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. Revenue is recognized when title and risk of loss for the products is transferred to the customer. Certain of our license agreements provide that the ultimate supply price is based on a percentage of the licensee s net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price we are entitled to receive on sales to the licensee. We receive the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. We record any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, we record the adjustments 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) or other applicable revenue recognition guidance. 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, which is management s best estimate of the earning period. Estimates of product life cycles are inherently

Table of Contents

uncertain 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 as we believe direct hours spent on the projects is the best indicator of our delivery of the obligation and earning process for the contract. 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 change the revenue recognition for contracts.

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.

Product 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 deductions for allowances for returns at Noven and Novogyne, respectively. Based on a review of available information, including actual product returns and remaining 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

Table of Contents

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

Until December 31, 2005 we 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 FASB Statement No. 123, Accounting for Stock-Based Compensation (SFAS 123), as amended by FASB Statement No. 148, Accounting for Stock-Based Compensation (SFAS 148). Accordingly, no compensation expense related to the granting of stock options has been recognized for the years ended December 31, 2005, 2004 and 2003.

As noted in the section New Accounting Standards , in December 2004, the FASB issued FASB Statement No. 123(R), Accounting for Stock-Based Compensation (SFAS 123(R)) that requires 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, 2005, 2004 and 2003 would have been reduced by 142%, 52% and 32%, respectively. As noted above, we accelerated vesting of certain stock options during 2005, which caused the amount of compensation expense calculated using the Black-Scholes option pricing model to be significantly higher than in prior years. Furthermore, as stated in the section New Accounting Standards , we started applying this statement on January 1, 2006, which we expect will result in compensation expenses of approximately $3.1 million (not including tax effects) in 2006, based on option grants unvested and outstanding at December 31, 2005. The foregoing amount does not include compensation expense for any equity awards that may be granted after January 1, 2006. However, these calculations use option valuation models that use highly subjective assumptions, including expected stock price volatility. Therefore, our results of operations could be materially different if different assumptions are used. In addition, the effect of applying the fair value method of accounting for stock options on reported net income for 2005, 2004 and 2003 may not be representative of the effects for future years because outstanding options vest over a period of several years, additional awards may be granted in future years and the acceleration of certain unvested stock options in 2005 may not be repeated.

Inventories

Inventories consist primarily of raw materials, work in process and finished goods for our commercial branded products and under certain circumstances may include pre-launch branded and generic products. Inventory costs include material, labor and manufacturing overhead. Inventories are stated at the lower of cost (first-in, first-out method or FIFO) or market and as appropriate, we reflect provisions necessary to reduce the carrying value of our inventories to net realizable value.

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

Table of Contents

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 write-down 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 provisions we establish.

We evaluate lower of cost or market separately for commercial and pre-launch inventories. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, remaining shelf life and current and expected orders from our collaboration partners based on market conditions, including levels of competition.

Pre-Launch Inventories

From time to time we may manufacture launch or commercial quantities of our branded or generic product candidates prior to the date that we anticipate that such products will receive FDA final marketing approval or the satisfactory resolution of patent infringement litigation, if any, involving the product but after the successful completion of the clinical development program and the initial filing of regulatory documents with the FDA. We will capitalize pre-launch quantities into inventories when we believe it is probable that (i) a future economic benefit will be derived from the commercialization of the product and/or the risk of pre-launch inventories is transferred to our collaborative partner, (ii) the FDA will approve the marketing of the product, (iii) we will validate our process for manufacturing the product within the specifications that have been or will be approved by the FDA for such product and (iv) particularly in the case of a generic product, we will prevail in any patent infringement litigation. In evaluating whether it is probable that we will derive future economic benefits from our pre-launch inventories and whether the pre-launch inventories are stated at the lower of cost or market, we consider, among other things, the remaining shelf life of that inventory, the current and expected market conditions, the amount of inventory on hand, the substance of communications with the FDA during the regulatory approval process and the views of patent and/or litigation counsel.

All of these criteria are re-assessed each reporting period in connection with our determination on whether pre-launch quantities of the applicable product are stated at lower of cost or market. We make provisions through cost of goods sold to reduce pre-launch inventories to their net realizable value.

We believe there are typically few risks and uncertainties concerning market acceptance of approved generic products because the branded product has an established demand, and a lower priced product may be substituted for that referenced brand product. In the case of branded products, we generally transfer all or a portion of the risk of pre-launch inventories to our collaborative partner.

The manufacture of pre-launch inventories requires us to, among other things, begin to validate our manufacturing processes in accordance with FDA regulations and the specifications for the product expected to be approved by the FDA. In order to be able to launch the product promptly upon the receipt of FDA approval, we must commence the validation process well before the date we

Table of Contents

anticipate the product will be approved. This process may entail a scale-up process in which, we evaluate and, as necessary, modify the equipment and processes employed in the manufacture of the new product to efficiently manufacture the product. We expense scale-up activities, including the raw material used in such activities. We capitalize direct and indirect manufacturing costs incurred during the manufacture of validation lots that we anticipate will be permitted to be sold by the FDA as well as the manufacture of additional product to meet estimated launch demand.

The manufacture of pre-launch inventories involves the risk that the FDA may not approve such product(s) for marketing on a timely basis or at all, that each approval may require additional or different testing and/or specifications than what was performed in the manufacture of such pre-launch inventory and/or that the results of related litigation may not be satisfactory. If any of these risks were to materialize with respect to a given product or if the launch of such product is significantly postponed, we may record additional provisions, which could be material. Shelf lives of pre-launch inventories generally exceed one year.

As of December 31, 2005 and 2004, we had pre-launch inventories pending final FDA approval broken down as follows (amounts in thousands):

	2005	2004
Work in process	$ 1,004	$ 5,032
Raw materials	1,397	5,774
Total	$ 2,401	$ 10,806

Pre-launch inventories as of December 31, 2005 consisted of the Daytrana product, which we, along with Shire, believe will receive final FDA approval and be commercially saleable in 2006. If Daytrana is not ultimately approved or this inventory is ultimately not commercially saleable, our purchase orders from Shire call for Shire to reimburse Noven the full cost of the inventory. Pre-launch inventories as of December 31, 2004 consisted of Noven s generic fentanyl patch. As a result of the FDA s decision to cease its review of our ANDA in September 2005, we wrote off the entire fentanyl patch inventory, which was $14.0 million at the time, with a charge of $9.5 million to our cost of products sold, representing our portion of the costs of the inventory as agreed with Endo.

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 as of December 31, 2005. 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.

Our future effective tax rate is based on estimates of expected income and enacted statutory tax rates, as applied to our operations. Significant judgment is required in making these determinations and the ultimate resolution of our tax return positions. Despite our belief that our tax return positions are correct, our policy is to establish accruals for tax contingencies that may result

Table of Contents

from examinations by tax authorities. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. It is reasonably possible that our effective tax rate and/or cash flows may be materially impacted by the ultimate resolution of our tax positions.

We are periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. Accordingly, we maintain tax contingency accruals for such potential assessments. The accruals are determined based upon our best estimate of possible assessments by the IRS or other taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances. The IRS audited our federal income tax returns for the years 2001 through 2003. We originally accrued $1.5 million based on our best estimate of possible assessment by the IRS at the time. During 2004, we reduced these accruals by $0.4 million based on changing facts and circumstances. During 2005, the IRS completed its audit of those years. In reaching final settlement with the IRS related to these tax years, we agreed to certain adjustments, primarily in the areas of research and development credits and to a lesser extent capitalization of software development costs and timing of depreciation and amortization. As a result of the final settlement, we reassessed our income tax contingency accruals to reflect the settlement. Based upon this reassessment, we recorded an additional $0.1 million reduction in these accruals during 2005, primarily related to interest charges on potential assessments. In addition, we paid the IRS during 2005 for all amounts settled, not including interest charges related to the 2002 and 2003 tax years, as those interest charges were not yet calculated as of December 31, 2005. As of December 31, 2005, we had $0.1 million in tax contingency accruals, related to these interest charges, which were paid in January 2006. In addition, as of December 31, 2005, we established $0.1 million in tax contingency accruals related to certain state tax positions we have determined are more likely than not to be challenged by state taxing authorities and we believe do not meet the probable criteria of being upheld.

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.

Intangible Asset

As of December 31, 2005, Novogyne had a long-term intangible asset of $32.4 million related to the acquisition of the marketing rights to CombiPatch®. The amortization of this asset is included in cost of sales in Novogyne s financial statements. 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. 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. Novogyne adjusts these assumptions from time to time based on new information as appropriate. If this analysis indicates that a possible impairment exists (undiscounted future cash flows are less than the carrying value), Novogyne would be required to

Table of Contents

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 would require Novogyne to apply a discount rate to the estimated undiscounted future cash flow of the asset. A material change in any of the assumptions made by Novogyne to calculate the discounted cash flows 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 assure that estimates of future cash flows have reflected the ultimate effect of the discontinued and currently ongoing HT studies, the recalls affecting CombiPatch®, the market share gains of a competitive combination HT patch, or the possible launch of additional combination HT therapies in 2006, 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.

Revenue Recognition

Revenues at Novogyne are recognized when all the risks and rewards of ownership have transferred to the customer, which occurs at the time of shipment of products. Revenues are reduced at the time of sale to reflect expected returns that are estimated based on historical experience. Additionally, provisions are made at the time of sale for all discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenue.

These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the impact of these sales deductions on gross sales for a reporting period. These estimates for revenue deductions are derived utilizing a combination of information received from third parties, including market data, inventory reports from its major wholesale customers, historical information and other analysis.

The following briefly describes the nature of each revenue deduction and how the related accruals are estimated by Novogyne:

The United States Medicaid program is a state-government-administered program that uses state and federal funds to provide assistance to certain vulnerable and needy individuals and families. In 1990, the Medicaid Drug Rebate Program was established to reduce state and federal expenditures for prescription drugs. Under the rebate program, rebates are paid to states based on drugs paid for by those states. Provisions for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, price increases, the impact of contracting strategies and specific terms in the individual state agreements. These provisions are then adjusted based upon the established re-filing process with individual states. For Medicaid, the calculation of rebates involves interpretation of relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Since Medicaid rebates are typically billed up to

Table of Contents

six months after the product is dispensed, any rebate adjustments may involve revisions of accruals for several quarters. Novogyne s management believes that due to Novartis extensive experience with Medicaid rebates, it is able to reasonably estimate rebates.

The products also participate in prescription drug savings programs that offer savings to patients that are eligible participants under United States Medicare programs. These savings vary based on a patient s current drug coverage and personal income levels. Provisions for the obligations under these programs are based on historical experience, trend analysis and current program terms. On January 1, 2006, an additional prescription drug benefit was added to the United States Medicare program. Individuals who have dual Medicaid/Medicare drug benefit eligibility had their Medicaid prescription drug coverage replaced by the new Medicare Part D coverage, provided by private prescription drug plans. The change will lead to a shift of plan participants between programs in which the products participate. The estimated impact of this shift that is related to 2005 sales has been reflected in Novogyne s sales accruals at the end of 2005 although the impact was relatively neutral to Novogyne s products.

Wholesaler chargebacks relate to contractual arrangements with certain indirect customers to sell products at prices that are lower than the list price charged to wholesalers. A wholesaler chargeback represents the difference between the invoice price charged to the wholesaler and the indirect customer s contract discount price. Provisions for estimating chargebacks are calculated using a combination of historical experience, product growth rates and the specific terms in each agreement. Wholesaler chargebacks are generally settled within a few weeks of incurring the liability.

Managed health care rebates are offered to key managed health care, group purchasing organizations and other direct and indirect customers to sustain and increase product market share. These rebate programs provide that the customer receive a rebate after attaining certain performance parameters relating to product purchases, formulary status and/or pre-established market share milestones relative to competitors. Since rebates are contractually agreed upon, rebates are estimated based on the specific terms in each agreement, historical experience and product growth rates. The sales performance of products subject to managed health care rebates and other contract discounts and levels of inventory in the distribution channel are tracked, and adjustments to the accrual are made periodically to reflect actual experience.

In order to evaluate adequacy of ending accrual balances, Novogyne uses both internal and external estimates of the level of inventory in the distribution channel and the rebate claims processing lag time. External data sources include periodic reports of wholesalers and purchased third party market data. Management internally estimates the inventory level in the retail channel and in transit.

It is customary in the pharmaceutical industry to allow returns of unused stocks within six months of shelf-life expiry. Novogyne s policy is that no product will be shipped with less than nine months of remaining shelf-life and Novogyne generally will accept returns due to expiration within twelve months after the product has expired. An allowance for estimated sales returns is recorded 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. Novogyne also considers trends and expectations for future demand and trade inventory levels. These policies cause a significant lag time between when a

Table of Contents

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 associated with recalls 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 different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Novogyne s product supply policy is to maintain inventories on a consistent level from year to year based on the pattern of consumption. Wholesaler inventory levels are monitored monthly based on gross sales volume, prescription volumes based on third party data and information received from the key wholesalers. Based on this information, the inventories on hand at wholesalers and other distribution channels were estimated to be approximately one month at December 31, 2005 and 2004. Novogyne believes the third party data sources of information are sufficiently reliable; however its accuracy cannot be independently verified.

Cash discounts are offered to customers to encourage prompt payment. Cash discounts, which are typically 2% of gross sales, are accrued at the time of sale.

Other sales discounts, such as consumer coupons and discount cards, are also offered. These discounts are recorded at the time of sale and estimated utilizing historical experience and the specific terms for each program.

Table of Contents

The following table describes the activity for the revenue deduction accruals by major category for the year ended December 31, 2005 (amounts in thousands):

	January 1, 2005	Payments	Income Statement Charge Adjustments of prior years	Current Year	December 31, 2005
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 560	$ (943)	$ (343)	$ 1,281	$ 555
Managed health care rebates	3,619	(7,502)	345	7,673	4,135
Chargebacks, including hospital chargebacks	79	(967)		970	82
Cash discounts, direct customer discounts & other discounts	235	(3,900)		4,482	817
Sales returns allowances	9,169	(3,937)	(2,385)	3,321	6,168
Total	$ 13,662	$ (17,249)	$ (2,383)	$ 17,727	$ 11,757

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 determining the 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.

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, 2005, Novogyne had litigation accruals of $4.9 million, with an expected insurance recovery of $3.5 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

Table of Contents

accruals and recoveries relating to Novogyne are estimated by Novartis (based on claims specifically attributable to Novogyne s products and Novogyne s insurance policies). Based on an analysis of the underlying data, the amounts recorded by Novogyne represent Novartis best estimate of litigation 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.

New Accounting Standards

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 currently account for abnormal amounts of idle facility expense, freight or wasted material (spoilage) as current-period charges and allocate fixed production overheads to inventory based on the normal capacity of the production facilities and recognize unallocated overheads as an expense in the period in which they are incurred. For the foregoing reasons, we do not anticipate that implementation of this statement will have a material impact on our results of operations and financial condition.

In December 2004, the FASB issued SFAS 123(R), which revises SFAS 123, and supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25) and amends SFAS No. 95 Statement of Cash Flows. SFAS 123(R) requires companies to recognize in their income statement the grant-date fair value of stock options and other equity-based compensation issued to employees and directors. Pro forma disclosure is no longer an alternative. We adopted SFAS 123(R) on January 1, 2006. This standard requires that compensation expense for most equity-based awards be recognized over the requisite service period, usually the vesting period, while compensation expense for liability-based awards (those usually settled in cash rather than stock) be re-measured to fair-value at each balance sheet date until the award is settled. Because we recognized no compensation cost for equity-based awards prior to the adoption of SFAS 123(R) s fair value method, we expect SFAS 123(R) will have a significant impact on our reported results of operations, although it will have no net impact on our overall financial position or cash flows.

Table of Contents

We use the Black-Scholes formula to estimate the value of stock-based compensation granted to employees and directors and expect to continue to use this acceptable option valuation model in 2006, but may consider switching to an alternative valuation model in the future, if we determine that such a model will produce a better estimate of fair value. Because SFAS 123(R) must be applied not only to new awards, but to previously granted awards that are not fully vested on the effective date, compensation cost for some previously granted options will be recognized under SFAS 123(R). However, had we adopted SFAS 123(R) in prior periods, the impact of that statement would have approximated the impact described in the disclosure of pro forma net income and earnings per share.

SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as previously required.

We will follow the modified prospective method, which requires us (i) to record compensation expense for the non-vested portion of previously issued awards that remain outstanding at the initial date of adoption and (ii) to record compensation expense for any awards issued or modified after January 1, 2006.

In December 2004, the FASB issued SFAS No. 153 Exchanges of Nonmonetary Assets, An Amendment of APB Opinion No. 29 (SFAS 153). SFAS 153 eliminates the exception for exchange of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. SFAS 153 is effective for non-monetary assets and exchanges occurring in the first quarterly period beginning after June 15, 2005. As we have no present intention to engage in exchanges of non-monetary assets, we do not anticipate that implementation of this statement will have a material impact on our results of operations and financial condition or cash flows.

In June 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections (SFAS 154). SFAS 154 replaces APB Opinion No. 20, Accounting Changes and FAS No. 3, Reporting Accounting Changes in Interim Financial Statements . SFAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle. SFAS 154 also requires that a change in method of depreciating or amortizing a long-lived non-financial asset be accounted for prospectively as a change in estimate, and correction of errors in previously issued financial statements should be termed a restatement. SFAS 154 is effective for accounting changes and correction of errors made in the first annual reporting period beginning after December 15, 2005. The implementation of SFAS 154 is not presently expected to have a material impact on our results of operations and financial condition and cash flows.

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

Not applicable.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements at page 90 of this report.

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

Not applicable.

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.

Table of Contents

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:

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 accounting principles generally accepted in the United States, 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, and because it is required to provide only reasonable, not absolute, assurance that its objectives are met, 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, 2005. 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, 2005, Noven s internal control over financial reporting is effective based on those criteria.

Deloitte & Touche LLP, Noven s independent registered public accounting firm, has issued an audit report on Noven s management s assessment of the company s internal control over financial reporting. This report appears on page 79.

Table of Contents

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, 2005, 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, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of

Table of Contents

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, 2005, 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, 2005 of the Company and our report dated March 13, 2006 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants
Miami, Florida
March 13, 2006

Table of Contents

Item 9B. Other Information.

As a result of the FDA s determination that our fentanyl ANDA was not approvable, Noven and Endo agreed effective December 31, 2005 to terminate the fentanyl portion of their license agreement as well as the fentanyl supply agreement between the parties. Noven also granted Endo a right of first negotiation with respect to any reformulated fentanyl patch that Noven may develop.

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 2006 Annual Meeting of Stockholders. 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 2006 Annual Meeting of Stockholders.

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, 2005:

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	4,004	$ 17.23	477
Equity Compensation Plans Not Approved by Security Holders	23	$ 12.58	
Total	4,027	$ 17.20	477

Table of Contents

(b) Information Concerning Security Ownership

The information is incorporated by reference to our Proxy Statement for our 2006 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions.

The information required by Item 13 is incorporated by reference to our Proxy Statement for our 2006 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by Item 14 is incorporated by reference to our Proxy Statement for our 2006 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See Index to Financial Statements at page 90 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.

Table of Contents

(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. 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.
10.2	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).
10.3	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.

Table of Contents

Exhibit Number	Description	Method of Filing
10.4	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).
10.5	Form of Employment Agreement (Change of 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 of Control) filed as Exhibit 10.1 of Noven s Form 8-K dated November 15, 2005 (File No. 0-17254).
10.6	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).
10.7	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).
10.8	Industrial Lease between Rhône-Poulenc Rorer Pharmaceuticals Inc. and Noven dated March 23, 1993 and effective February 16, 1993 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.20 of Noven s Form 10-K for the year ended December 31, 1993 (File No. 0-17254).
10.9	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).
10.10	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).
10.11	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).

Table of Contents

Exhibit Number	Description	Method of Filing
10.12	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).
10.13	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).
10.14	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer Pharmaceuticals, 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).
10.15	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).
10.16	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).
10.17	License Agreement between Noven and Novartis Pharma AG dated as of November 3, 2000 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 2000 (File No. 0-17254).
10.18	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).
10.19	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).

Table of Contents

Exhibit Number	Description	Method of Filing
10.20	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).
10.21	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).
10.22	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).
10.23	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).
10.24	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).
10.25	Toll Conversion and Supply Agreement among Shire US Inc., Shire Pharmaceuticals Group PLC and Noven, dated as April 7, 2003 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.25 of Noven s Form 10-K for the year ended December 31, 2002 (File No. 0-17254).
10.26	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).
10.27	Agreement between Shire Pharmaceuticals Ireland Limited and Noven dated March 6, 2006.**	Filed herewith.
10.28	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).

Table of Contents

Exhibit Number	Description	Method of Filing
10.29	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).
10.30	Termination Agreement between Noven and Endo Pharmaceuticals Inc. effective as of December 31, 2005 (with certain provisions omitted pursuant to Rule 24b-2).	Filed herewith.
10.31	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).
10.32	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).
10.33	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).
10.34	Letter Agreement between Noven and Proctor & Gamble Pharmaceuticals, Inc., dated December 22, 2004 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.36 of Noven s Form 10-K for the year ended December 31, 2004 (File No. 0-17254).
10.35	Industrial Long-Term Lease, dated February 22, 2005, between Noven and Deerwood Commerce Center LLC.**	Incorporated by reference to Exhibit 10.37 of Noven s Form 10-K for the year ended December 31, 2004 (File No. 0-17254).
10.36	Changes to Compensation and Reimbursement Practices for Non-employee Directors.*	Incorporated by reference to Noven s Form 8-K dated May 23, 2005 (File No. 0-17254).
10.37	Noven Pharmaceuticals, Inc. Nonqualified Deferred Compensation Plan.*	Incorporated by reference to Exhibit 10.2 of Noven s Form 8-K dated November 15, 2005 (File No. 0-17254).

Table of Contents

Exhibit Number	Description	Method of Filing
10.38	Base Salaries for Executive Officers for 2006.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated December 8, 2005 (File No. 0-17254).
11	Computation of Earnings per Share.	Filed herewith.
21	Subsidiaries of the Registrant.	Filed herewith.
23.1	Consent of Deloitte & Touche LLP.	Filed herewith.
23.2	Consent of PricewaterhouseCoopers LLP.	Filed herewith.
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.

Table of Contents

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 14, 2006 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 14, 2006
By: /s/Diane M. Barrett Diane M. Barrett (Vice President & Chief Financial Officer)	Principal Financial and Accounting Officer	March 14, 2006
By: Sidney Braginsky	Director	
By: /s/John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 14, 2006
By: /s/Donald A. Denkhaus Donald A. Denkhaus	Director	March 14, 2006
By: /s/Pedro P. Granadillo Pedro P. Granadillo	Director	March 14, 2006
By: /s/Robert G. Savage	Director	March 14, 2006

	Robert G. Savage		
By:	/s/Wayne P. Yetter	Director	March 14, 2006
	Wayne P. Yetter		

Table of Contents

INDEX TO FINANCIAL STATEMENTS

NOVEN PHARMACEUTICALS, INC.

Table of Contents

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, 2005 and 2004, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2005. 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, 2005, 2004, and 2003. Noven s equity in Vivelle Ventures LLC of $23,243,000 and $26,233,000 at December 31, 2005 and 2004, respectively, and Noven s share of that joint venture s income of $24,655,000, $17,641,000 and $17,094,000 for the years ended December 31, 2005, 2004, 2003, 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 2005, 2004, and 2003, 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, 2005 and 2004 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, 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, 2005, 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 13, 2006 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 based on our audits.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants
Miami, Florida
March 13, 2006

Table of Contents

NOVEN PHARMACEUTICALS, INC.
Balance Sheets
December 31, 2005 and 2004
(in thousands, except share data)

	2005	2004
Assets		
Current Assets:		
Cash and cash equivalents	$ 66,964	$ 93,958
Short-term investments available-for-sale, at fair value	17,900	
Accounts receivable trade (less allowance for doubtful accounts of $53 in 2005 and $64 in 2004)	2,919	5,395
Accounts receivable Novogyne, net	8,912	10,098
Inventories	7,861	15,988
Net deferred income tax asset, current portion	6,000	6,700
Prepaid income taxes	7,697	9,344
Prepaid and other current assets	1,357	1,238
	119,610	142,721
Property, plant and equipment, net	34,455	22,587
Other Assets:		
Investment in Novogyne	23,243	26,233
Net deferred income tax asset	6,373	8,239
Patent development costs, net	2,211	2,174
Deposits and other assets	18	21
	31,845	36,667
	$ 185,910	$ 201,975
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,812	$ 12,176
Capital lease obligation current portion	121	114
Accrued liability Shire	5,488	10,587
Accrued compensation and related liabilities	5,771	5,762
Other accrued liabilities	2,124	3,015
Deferred rent credit	89	
Deferred contract revenues	1,481	2,076
Deferred license revenues current portion	7,602	11,642
	28,488	45,372
Long-Term Liabilities:		
Capital lease obligation		121
Deferred rent credit	748	
Deferred license revenues	16,053	27,443

	45,289	72,936
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 23,617,221 in 2005 and 23,481,264 in 2004	2	2
Additional paid-in capital	89,846	88,236
Retained earnings	50,773	40,801
	140,621	129,039
	$ 185,910	$ 201,975

The accompanying notes are an integral part of these statements.

Table of Contents

NOVEN PHARMACEUTICALS, INC.
Statements of Operations
Years Ended December 31, 2005, 2004 and 2003
(in thousands, except per share amounts)

	2005	2004	2003
Revenues:			
Product revenues Novogyne:			
Product sales	$ 19,910	$ 18,798	$ 15,932
Royalties	6,444	5,204	4,978
Total product revenues Novogyne	26,354	24,002	20,910
Product revenues third parties	14,097	12,869	16,206
Total product revenues	40,451	36,871	37,116
Contract and license revenues:			
Contract	2,528	5,021	2,024
License	9,553	3,999	4,026
Contract and license revenues	12,081	9,020	6,050
Net revenues	52,532	45,891	43,166
Expenses:			
Cost of products sold Novogyne	13,547	11,413	8,753
Cost of products sold third parties	20,500	9,101	11,092
Research and development	13,215	9,498	7,719
Marketing, general and administrative	16,915	17,271	15,858
Total expenses	64,177	47,283	43,422
Loss from operations	(11,645)	(1,392)	(256)
Equity in earnings of Novogyne	24,655	17,641	17,094
Interest income, net	2,242	999	659
Income before income taxes	15,252	17,248	17,497
Provision for income taxes	5,280	6,024	6,301
Net income	$ 9,972	$ 11,224	$ 11,196

Basic earnings per share	$ 0.42	$ 0.48	$ 0.50
Diluted earnings per share	$ 0.42	$ 0.46	$ 0.49
Weighted average number of common shares outstanding:			
Basic	23,566	23,332	22,544
Diluted	23,981	24,305	22,989

The accompanying notes are an integral part of these statements.

Table of Contents

NOVEN PHARMACEUTICALS, INC.
Statements of Stockholders Equity
Years Ended December 31, 2005, 2004 and 2003
(in thousands)

	Common Stock		Additional Paid-in	Retained	
	Shares	Amount	Capital	Earnings	Total
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
Issuance of shares pursuant to stock option plan, net	136		1,290		1,290
Tax benefit from exercise of stock options			281		281
Compensation expense related to accelerated options			39		39
Net income				9,972	9,972
Balance at December 31, 2005	23,617	$ 2	$ 89,846	$ 50,773	$ 140,621

The accompanying notes are an integral part of these statements.

Table of Contents

NOVEN PHARMACEUTICALS, INC.
Statements of Cash Flows
Years Ended December 31, 2005, 2004 and 2003
(in thousands)

	2005	2004	2003
Cash flows from operating activities:			
Net income	$ 9,972	$ 11,224	$ 11,196
Adjustments to reconcile net income to net cash flows provided by operating activities:			
Depreciation and amortization	2,713	2,285	2,278
Loss on disposal of equipment		347	
Write-off of fentanyl inventories deemed non-saleable	9,475		
Amortization of patent costs	449	389	341
Amortization of non-competition agreement		167	400
Amortization of deferred rent credit	(75)		
Income tax benefits on exercise of stock options	281	3,034	527
Deferred income tax (benefit) expense	2,566	5,236	(6,944)
Compensation expense related to accelerated options	39		
Non-cash expense related to issuance of stock to outside directors and options to charitable organization		34	31
Recognition of deferred license revenues	(9,553)	(3,999)	(4,026)
Equity in earnings of Novogyne	(24,655)	(17,641)	(17,094)
Distributions from Novogyne	26,187	18,083	21,739
Changes in operating assets and liabilities:			
Decrease (increase) in accounts receivable trade, net	2,476	(1,586)	550
Decrease (increase) in accounts receivable Novogyne, net	1,186	(3,778)	(3,739)
(Increase) decrease in inventories	(1,348)	(10,788)	413
Decrease (increase) in prepaid income taxes	3,105	(5,497)	(483)
Increase in prepaid and other current assets	(119)	(173)	(524)
Decrease (increase) in deposits and other assets	3	(7)	
(Decrease) increase in accounts payable and accrued expenses	(6,364)	8,206	(1,092)
(Decrease) increase in accrued liability Shire	(5,099)	10,497	90
Increase in accrued compensation and related liabilities	9	2,028	185
(Decrease) increase in other accrued liabilities	(891)	(575)	727
(Decrease) increase in deferred contract revenue, net	(595)	1,304	(57)
Increase in deferred license revenue		6,500	25,000
Amounts reimbursable to Shire and offset against deferred license revenue related to Daytrana approval	(5,877)	(13,421)	(414)
Cash flows provided by operating activities	3,885	11,869	29,104
Cash flows from investing activities:			
Purchases of property, plant and equipment, net	(13,669)	(6,529)	(4,400)
Payments for patent development costs, net	(486)	(586)	(322)
Purchases of short-term investments	(516,505)		
Proceeds from sale of short-term investments	498,605		
Cash flows used in investing activities	(32,055)	(7,115)	(4,722)

Cash flows from financing activities:			
Issuance of common stock from exercise of stock options	1,290	5,924	1,617
Purchase and retirement of common stock			(1,289)
Payments under capital leases	(114)	(101)	(13)
Cash flows provided by financing activities	1,176	5,823	315
Net (decrease) increase in cash and cash equivalents	(26,994)	10,577	24,697
Cash and cash equivalents, beginning of year	93,958	83,381	58,684
Cash and cash equivalents, end of year	$ 66,964	$ 93,958	$ 83,381

The accompanying notes are an integral part of these statements.

Table of Contents

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 products delivery systems marketed under the brand names Vivelle-Dot, Vivelle® 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 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, specifically estimates related to (a) estimating when the license period begins and determining the period of recognition when revenues have been earned over estimated product life cycles or length of patents and (b) determining when price adjustment provisions, minimum fee payments and/or milestone and similar payments that are dependent on licensee supporting data have been earned, (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) estimates related to allowance for returns related to product recalls at Noven, accrued liabilities, income and other tax accruals, contingencies and litigation and (viii) impairment of long lived assets.

Table of Contents

The most significant estimates made by the management of Novogyne impacting Noven s financial statements include: (i) Novogyne s testing for impairment of the long-term intangible asset related to the acquisition of the marketing rights to CombiPatch®, (ii) Novogyne s estimates related to sales allowances and returns at Novogyne and (iii) Novogyne s provisions for product liability claims and contingencies and anticipated recovery of insurance related receivables.

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. Cash and cash equivalents as of December 31, 2005 and 2004, consisted primarily of overnight money market accounts, time deposits and money market funds with original maturities of three months or less at the date of purchase.

INVESTMENTS AVAILABLE-FOR-SALE:

Beginning in the first quarter of 2005, Noven invested a portion of its cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of Statement of Financial Accounting Standards (SFAS) No. 115 Accounting for Certain Investments in Debt and Equity Securities . Despite the long-term nature of their stated contractual maturities, these securities have provisions that allow for liquidation in the short-term. Accordingly, the short-term investments are reported at fair value, with any related unrealized gains and losses included in comprehensive income as a separate component of stockholder s equity, net of applicable taxes. Realized gains and losses and interest and dividends are included in interest income or interest expense, as appropriate.

As of December 31, 2005, short-term investments that are classified as available-for-sale consists of approximately $15.0 million in tax-exempt municipal auction rate securities and $2.9 million in tax-exempt variable rate demand bonds. For all these investments, the market value was equal to the amortized costs as of December 31, 2005. Therefore, there were no unrealized gains or losses as of that date. Furthermore, although the contractual maturities for all of these investments are greater than one year, they are classified as short-term investments available-for-sale due to the fact that interest rate auctions will occur periodically within the next year for the auction rate securities, and the variable rate demand bonds can be tendered for purchase at par whenever rates reset.

INVENTORIES:

Inventories consist primarily of raw materials, work in process and finished goods for our commercial branded products and under certain circumstances may include pre-launch branded and generic products. Inventory costs include material, labor and manufacturing overhead. As appropriate, Noven reflects provisions necessary to reduce the carrying value of its inventories to net realizable value. To date, Noven has not experienced any difficulty acquiring materials necessary to manufacture its products. Certain raw materials and

Table of Contents

components used in the manufacture of its products (including essential polymer adhesives and other critical components) are, however, available from limited sources, and in some cases, a single source. No assurance can be given that Noven will not experience difficulty in the future. Other than products produced for commercial sale or to meet the requirements for production of pre-launch inventories, Noven s policy is to immediately recognize as expense all inventory purchased for research and development purposes.

Commercial Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or market. Noven evaluates lower of cost or market separately for commercial and pre-launch inventories. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, remaining shelf life and current and expected orders from Noven s collaboration partners based on market conditions, including levels of competition.

Pre-Launch Inventories

From time to time Noven may manufacture launch or commercial quantities of branded or generic product candidates prior to the date that Noven anticipates that such products will receive FDA final marketing approval or the satisfactory resolution of the patent infringement litigation, if any, involving the product but after the successful completion of the clinical development program and the initial filing of regulatory documents with the FDA. Noven will capitalize pre-launch quantities into inventories when Noven believes it is probable that (i) a future economic benefit will be derived from the commercialization of the product and/or the risk of pre-launch inventories is transferred to Noven s collaborative partner, (ii) the FDA will approve the marketing of the product, (iii) Noven will validate its process for manufacturing the product within the specifications that have been or will be approved by the FDA for such product and (iv) particularly in the case of a generic product, Noven will prevail in any patent infringement litigation. In evaluating whether it is probable that Noven will derive future economic benefits from its pre-launch inventories and whether the pre-launch inventories are stated at the lower of cost or market, Noven considers, among other things, the remaining shelf life of that inventory, the current and expected market conditions, the amount of inventory on hand, the substance of communications with the FDA during the regulatory approval process and the views of patent and/or litigation counsel.

All of these criteria are re-assessed each reporting period in connection with Noven s determination on whether pre-launch quantities of the applicable product are stated at lower of cost or market. Noven makes provisions through cost of goods sold to reduce pre-launch inventories to their net realizable value.

Noven believes there are typically few risks and uncertainties concerning market acceptance of approved generic products because the branded product has an established demand, and the lower priced product may be substituted for the referenced brand product. For Noven s branded products, Noven generally transfers all or a portion of the risk of pre-launch inventories to its collaborative partner.

Table of Contents

The manufacture of pre-launch inventories requires Noven to, among other things, begin to validate Noven s manufacturing processes in accordance with FDA regulations and the specifications for the product expected to be approved by the FDA. In order to be able to launch the product promptly upon the receipt of FDA approval, Noven must commence the validation process well before the date Noven anticipates the product will be approved. This process may entail a scale-up process in which, Noven evaluates and, as necessary, modifies the equipment and processes employed in the manufacture of the new product to efficiently manufacture the product. Noven expenses scale-up activities, including the raw material used in such activities. Noven capitalizes direct and indirect manufacturing costs incurred during the manufacture of validation lots that it anticipates that it will be permitted to sell by the FDA as well as the manufacture of additional product to meet estimated launch demand.

The manufacture of pre-launch inventories involves the risk that the FDA may not approve such product for marketing on a timely basis or at all, that each approval may require additional or different testing and/or specifications than what was performed in the manufacture of such pre-launch inventory and/or that the results of related litigation may not be satisfactory. If any of these risks were to materialize with respect to a given product or if the launch of such product is significantly postponed, Noven may record additional provisions, which could be material. Shelf lives of pre-launch inventories generally exceed one year.

The following are the major classes of inventories as of December 31, 2005 and 2004 (in thousands):

	December 31, 2005			December 31, 2004		
	Commercial	Pre-Launch	Total	Commercial	Pre-Launch	Total
Finished goods	$ 760	$	$ 760	$ 610	$	$ 610
Work in progress	1,278	1,004	2,282	1,490	5,032	6,522
Raw materials	3,422	1,397	4,819	3,082	5,774	8,856
	$ 5,460	$ 2,401	$ 7,861	$ 5,182	$ 10,806	$ 15,988

Pre-launch inventories as of December 31, 2005 consisted of Noven s Daytrana product, which Noven, along with Shire, believes will receive final FDA approval and be commercially saleable in 2006. If Daytrana is not ultimately approved or this inventory is ultimately not commercially saleable, Noven s purchase orders from Shire call for Shire to reimburse Noven the full cost of the inventory (see Contract and License Agreements Shire Collaboration). Pre-launch inventories as of December 31, 2004 consisted of Noven s generic fentanyl patch. As a result of the FDA s decision to cease its review of Noven s fentanyl Abbreviated New Drug Application (ANDA) in September 2005, Noven wrote off the inventory, which was $14.0 million at the time, with a charge of $9.5 million to cost of products sold, representing Noven s portion of the costs of the inventory as agreed with Endo (see Contract and License Agreements Endo Collaboration).

Table of Contents

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, 2005 and 2004, approximately $1.2 million and $0.9 million, respectively, of these costs were capitalized.

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

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. As a result of the FDA s decision to cease review of Noven s fentanyl ANDA, Noven reviewed for impairment all long-lived assets associated with its fentanyl patch and determined that no impairment resulted during the year ended December 31, 2005.

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 and included in cost of products sold.

Table of Contents

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. Noven s policy is to accrue for estimated legal fees and settlement costs related to litigation as cases are filed. 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 and tax contingencies require Noven to make assumptions on estimated liabilities related to those matters (see Notes 8 and 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 sanofi-aventis (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. 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

Table of Contents

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) or other applicable revenue recognition guidance. 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, which is management s best estimate of the earning period.

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

Table of Contents

Product 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.

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. Noven s policy is to immediately expense manufacturing overhead variances.

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, which includes costs associated with, among other things, product formulation, pre-clinical testing, clinical studies, regulatory and medical affairs, production of product for clinical and regulatory purposes, production engineering for developmental products, and the personnel associated with each of these functions. Research and development expenses for 2004 and 2003 have been revised to exclude certain amounts that are now included in cost of products sold.

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 an estimate of the potential dilution that would occur if securities or other contracts to issue common stock that we issue 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, 2005, 2004 and 2003 was 2,019,863, 1,360,983 and 2,107,959 shares, respectively, which amounts represent out-of-the-money stock options.

COMPREHENSIVE INCOME:

For the years ended December 31, 2005, 2004 and 2003, total comprehensive income was equal to net income.

Table of Contents

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 equity compensation plans, or adopt the fair value method of accounting prescribed by SFAS 123. For 2005 and prior periods, Noven elected to continue to account for its equity compensation plans using APB 25, and therefore no stock-based employee compensation cost was 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 and the number of shares of common stock was fixed on the date of grant.

The following table illustrates the effect on net income and earnings per share for the periods ended December 31, 2005, 2004 and 2003 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

	2005	2004	2003
Net income:			
As reported	$ 9,972	$ 11,224	$ 11,196
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(14,145)	(5,842)	(3,596)
Pro forma	$ (4,173)	$ 5,382	$ 7,600
Basic earnings per share:			
As reported	$ 0.42	$ 0.48	$ 0.50
Pro forma	$ (0.18)	$ 0.23	$ 0.34
Diluted earnings per share:			
As reported	$ 0.42	$ 0.46	$ 0.49
Pro forma	$ (0.18)	$ 0.22	$ 0.33

SFAS 123 requires the use of option valuation models that require the input of highly subjective assumptions, including expected stock price volatility. The fair value of each option granted during 2005, 2004 and 2003 is estimated to be $8.64, $13.10 and $7.01, respectively, on the date of the grant using the Black-Scholes option-pricing model with the assumptions listed below:

Table of Contents

	2005	2004	2003
Volatility	69.0%	69.0%	80.0%
Risk free interest rate	4.30%	3.49%	3.22%
Expected life (years)	5	5	5

As noted in the section Recent Accounting Pronouncements , effective January 1, 2006, Noven adopted Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment (SFAS 123(R)), which requires compensation expense associated with stock options be recognized in Noven s Statement of Operations, rather than as historically presented as a pro forma footnote disclosure in Noven s financial statements. In order to eliminate some of the future compensation expense that Noven would otherwise recognize in its Statement of Operations upon adoption of SFAS 123(R), during 2005 the Compensation and Stock Option Committee of the Board of Directors of Noven approved the acceleration of vesting of certain stock options under the Noven 1999 Long-Term Incentive Plan. As a result of this action, options to purchase approximately 1.1 million shares of Noven s common stock became immediately exercisable, including options held by Noven s executive officers to purchase approximately 455,000 shares. Noven recorded an immaterial charge to compensation expense during 2005 due to the acceleration of a nominal amount of in-the-money options. As a result of the acceleration, during 2005, approximately $10.1 million of future compensation expense, net of applicable income taxes, was eliminated from Noven s future Statement of Operations and included in the pro forma footnote disclosure above for 2005. At December 31, 2005, unamortized compensation expense related to outstanding unvested options, as determined in accordance with SFAS 123, that Noven expects to record in future years is approximately $8.3 million before the effect of income taxes, of which $3.1 million, $2.7 million, $1.8 million and $0.7 million is expected to be incurred in 2006, 2007, 2008 and 2009. Noven will incur additional expense in future years related to new and modified awards granted in the future that cannot yet be quantified.

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.

Table of Contents

CONCENTRATIONS OF CREDIT RISK:

Noven s customers currently consist of Novogyne, Novartis Pharma and a limited number of other 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. As of December 31, 2005, Noven had $42.4 million in two money market funds.

RECLASSIFICATION:

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

RECENT ACCOUNTING PRONOUNCEMENTS:

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 currently accounts for abnormal amounts of idle facility expense, freight or wasted material (spoilage) as current-period charges and allocates fixed production overheads to inventory based on the normal capacity of the production facilities and recognizes unallocated overheads as an expense in the period in which they are incurred. For the foregoing reasons, Noven does not anticipate that implementation of this statement will have a material impact on results of operations and financial condition.

In December 2004, the FASB issued SFAS 123(R), which revises SFAS 123 and supersedes APB 25 and amends SFAS No. 95 Statement of Cash Flows. SFAS 123(R) requires companies to recognize in their income statement the grant-date fair value of stock options and other equity-based compensation issued to employees and directors. Pro forma disclosure is no longer an alternative. Noven adopted SFAS 123(R) on January 1, 2006. This standard requires that compensation expense for most equity-based awards be recognized over the requisite service period, usually the vesting period, while compensation expense for liability-based awards (those usually settled in cash rather than stock) be re-measured to fair-value at each balance sheet date until the award is settled. Because Noven recognized no compensation cost for equity-based awards prior to the adoption of SFAS 123(R) s fair value method, Noven expects that SFAS 123(R) will have a significant impact on Noven s results of

Table of Contents

operations, although it will have no net impact on Noven s overall financial position or cash flows.

Noven uses the Black-Scholes formula to estimate the value of stock-based compensation granted to employees and directors and expects to continue to use this option valuation model in 2006, but may consider switching to an alternative valuation model in the future, if Noven determines that such a model will produce a better estimate of fair value. Because SFAS 123(R) must be applied not only to new awards, but to previously granted awards that are not fully vested on the effective date of Noven s adoption of SFAS 123(R), compensation cost for some previously granted options will be recognized under SFAS 123(R). However, had Noven adopted SFAS 123(R) in prior periods, the impact of that Statement would have approximated the impact described in the disclosure of pro forma net income and earnings per share.

SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as previously required.

Noven will follow the modified prospective method, which requires it (i) to record compensation expense for the non-vested portion of previously issued awards that remain outstanding at the initial date of adoption and (ii) to record compensation expense for any awards issued or modified after January 1, 2006.

In December 2004, the FASB issued SFAS No. 153 Exchanges of Nonmonetary Assets, An Amendment of APB Opinion No. 29 (SFAS 153). SFAS 153 eliminates the exception for exchange of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. SFAS 153 is effective for non-monetary assets and exchanges occurring in the first quarterly period beginning after June 15, 2005. As Noven has no present intention to engage in exchanges of non-monetary assets, Noven does not anticipate that implementation of this statement will have a material impact on its results of operations and financial condition.

In June 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections (SFAS 154). SFAS 154 replaces APB Opinion No. 20, Accounting Changes and FAS No. 3, Reporting Accounting Changes in Interim Financial Statements . SFAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle. SFAS 154 also requires that a change in method of depreciating or amortizing a long-lived non-financial asset be accounted for prospectively as a change in estimate, and correction of errors in previously issued financial statements should be termed a restatement. SFAS 154 is effective for accounting changes and correction of errors made in the first annual reporting period beginning after December 15, 2005. The implementation of SFAS 154 is not presently expected to have a material impact on Noven s results of operations and financial condition.

Table of Contents

3. CASH FLOW INFORMATION:

Cash payments for income taxes were $1.6 million, $5.4 million and $13.2 million in 2005, 2004 and 2003, respectively. Cash payments for interest were $12,000, $18,000 and $1,000 in 2005, 2004 and 2003, respectively.

Non-cash Operating Activities

In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. In April 2005, 2004 and 2003, Novogyne paid $1.5 million, $1.7 million and $1.7 million, respectively, to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state income tax payments. These payments were deemed a distribution to Noven from Novogyne.

Noven recorded a $0.3 million, $3.0 million and $0.5 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 2005, 2004 and 2003, respectively.

Non-cash Investing Activities

In 2005 Noven recorded approximately $0.9 million in leasehold improvements as a deferred rent credit relating to landlord-funded leasehold improvements. See Note 7 Operating and Capital Leases.

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, 2005 and 2004 (in thousands, except estimated useful lives):

	2005	2004	Estimated Useful Lives (in years)
Land	$ 2,540	$ 2,540	
Building and improvements	3,231	3,166	40
Leased property and leasehold improvements	19,231	12,655	10-31
Manufacturing and other equipment	21,628	15,193	3-10
Furniture	1,734	1,439	10
Software and software development costs	4,238	3,028	3
	52,602	38,021	
Less accumulated depreciation and amortization	(18,147)	(15,434)	
	$ 34,455	$ 22,587	

Table of Contents

5. CONTRACT AND LICENSE AGREEMENTS:

HORMONE THERAPY COLLABORATIONS

Noven has license agreements relating to its hormone therapy products 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 advanced estrogen delivery system in Canada. The agreement provides for royalty payments based on sales by Novogyne and Novartis Canadian affiliate.

Aventis Licenses

Noven has two license agreements with Aventis. These agreements grant Aventis the right to market Noven s original 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 advanced 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 ($1.2 million as of December 31, 2005), 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, 2005 and 2004, the carrying amount of the leased property and deferred revenues was $4.1 million and $4.3 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 original estrogen transdermal delivery system in all countries other than the United States, Canada and Japan.

Table of Contents

Novartis Pharma License of Estradot®

In November 2000, Noven entered into an exclusive license agreement with Novartis Pharma pursuant to which Noven s advanced transdermal estrogen delivery system under the name Estradot® in all countries other than the United States, Canada and Japan. The agreement also grants Novartis Pharma marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by Noven. Noven received an up-front license payment of $20.0 million upon execution of the agreement. The up-front payment was deferred and is being recognized as license revenues over 10 years beginning in the fourth quarter of 2000, which is the estimated life of the product. 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. Novogyne agreed to indemnify Noven against Noven s obligation 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 10 years beginning in the first quarter of 2001, which is the estimated life of the product. 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. Due to current regulatory requirements in Europe, Novartis Pharma has elected not to complete development of a next generation combination estrogen/progestin patch.

ENDO COLLABORATION

In July 2003, Noven submitted an ANDA to the FDA seeking approval to market a generic fentanyl patch and Noven entered into an agreement with Endo in the first quarter of 2004 granting Endo the exclusive right to market Noven s fentanyl patch in the United States. Noven received an up-front payment of $8.0 million from Endo, of which $6.5 million was allocated to license revenue for the fentanyl patch and the remaining $1.5 million was allocated based on fair value to fund feasibility studies that seek to determine whether certain compounds identified by the parties could be delivered through Noven s transdermal patch

Table of Contents

technology. Noven s agreement provides that Endo would fund and manage clinical development of those compounds proceeding into clinical trials.

In July 2005, the FDA issued a public advisory that it is investigating reports of death and other serious side effects from overdoses involving both the branded and generic fentanyl patches. In September 2005, the FDA advised Noven that it did not expect to approve Noven s ANDA and was consequently ceasing its review of Noven s ANDA, based on the FDA s assessment of potential safety concerns related to the higher drug content in Noven s generic product versus the branded product. The FDA subsequently confirmed in writing that our fentanyl ANDA was not approvable.

At the outset of the license Noven and Endo agreed that Noven would manufacture initial launch quantities of its fentanyl patch prior to receipt of final regulatory approval from the FDA and that the parties would share the cost of any non-saleable fentanyl inventories in accordance with an agreed-upon formula. As a result of the FDA s decision to cease review of Noven s ANDA, Noven deemed the entire $14.0 million of fentanyl patch inventories to be non-saleable and recorded a $9.5 million charge to cost of products sold in the third quarter of 2005. This charge represents the portion of the cost of the existing fentanyl inventories and purchasing commitments for raw materials allocable to Noven under the contractual formula. Endo was responsible for the remaining $4.5 million of the fentanyl patch production costs, which they paid Noven in the fourth quarter of 2005 less $2.6 million Noven owed Endo for fentanyl raw materials. In addition, Noven incurred approximately $0.4 million in costs associated with disposal and destruction of fentanyl inventories in the fourth quarter of 2005, which was charged to costs of products sold in that quarter.

Noven is currently evaluating the feasibility of reformulating the fentanyl patch to address the FDA s concerns. Due to the FDA s determination that Noven s fentanyl ANDA was not approvable, Noven and Endo agreed in December 2005 to terminate the fentanyl portion of the license agreement as well as the fentanyl supply agreement between the parties. As a result of the termination and the fact that Noven had no obligation to Endo and no continuing involvement related to the fentanyl license agreement, Noven earned the remaining $5.7 million of previously deferred license revenue and recognized it as license revenue in the fourth quarter of 2005.

SHIRE COLLABORATION

Noven has developed a transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder with the proposed brand name Daytrana. 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 2004 and 2005, Noven and Shire conducted additional clinical trials that were intended to address clinical issues raised in the not approvable letter Noven received from the FDA in April 2003 relating to Noven s New Drug Application (NDA) for Daytrana In June 2005, Noven submitted an amendment to the NDA that included new trial results, and in December 2005, Noven received an approvable letter from the FDA for Daytrana . The approvable letter

Table of Contents

contains proposed revisions to labeling, as well as requests for data clarification, post-marketing surveillance, and post-marketing studies. In February 2006, Noven provided the FDA with a resubmission to the Daytrana NDA intended to address the issues presented in the approvable letter. In March 2006, the FDA advised Noven that Noven s resubmission was complete and that April 9, 2006 had been established as the user fee goal date for the FDA to complete its review of the resubmission. In February 2006, Shire and Noven agreed to reduce the amount Shire may require Noven to pay to repurchase the product rights to Daytrana under certain circumstances from $5.0 million to $4.0 million.

Beginning in the fourth quarter of 2003, Noven has been recording reimbursements to Shire for Shire s direct costs and certain direct incremental costs incurred by Noven as requested by Shire in pursuit of Daytrana regulatory approval. These reimbursements have been recorded as a reduction of a portion of the $21.0 million that is nonrefundable deferred license revenue previously received from Shire ($25.0 million license payment less the $4.0 million repurchase right). Because Shire had made a significant investment related to licensing Daytrana, Shire wanted to manage the development program in order to advance Daytrana toward approval. Therefore, Noven effectively agreed to reimburse Shire a portion of Shire s non-refundable license payment for certain costs Shire incurred in pursuit of approval. Furthermore, due to the fact Shire requested that Noven incur certain direct incremental costs in pursuit of approval, Noven treated such costs as reimbursements as well. Such reimbursements and direct incremental costs did not impact Noven s research and development expenses in 2005, 2004 or 2003, although the reimbursements or amounts reimbursable to Shire reduced and will reduce Noven s cash position and also reduced and will continue to reduce the amount of deferred revenues that Noven may recognize in future periods. As of December 31, 2005, $4.8 million remained in deferred license revenue, of which $4.0 million is subject to Shire s repurchase right and is therefore considered refundable. Noven believes that future reimbursements to Shire will not exceed the $0.8 million, which is the remaining amount of non-refundable deferred license revenue.

As described above in Summary of Significant Accounting Policies Inventories Pre-Launch Inventories , as of December 31, 2005, Noven s inventories include $2.4 million of Daytrana pre-launch inventories. In the case Daytrana is not ultimately approved or this inventory is ultimately not commercially saleable, the terms of Noven s agreement with Shire call for Shire to reimburse Noven the full cost of the inventory.

In June 2004, Noven 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. No such development milestones had been earned as of December 31, 2005. 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

Table of Contents

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 indicated that it is working to identify a clinical strategy intended to address the FDA s safety concerns related to this product. During 2004, Noven earned $4.4 million under the P&G Pharmaceuticals collaboration. No development milestones under this collaboration were earned for the period ended December 31, 2005.

OTHER AGREEMENTS

Noven has entered into other developmental agreements for feasibility of certain compounds. In 2005, Noven received approximately $1.7 million related to these agreements.

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, 2005, 2004 and 2003 are as follows (in thousands):

	2005	2004	2003
Gross revenues	$ 136,901	$ 124,791	$ 120,282
Sales allowances	14,408	13,154	11,279
Sales returns allowances	936	6,224	7,926
Sales allowances and returns	15,344	19,378	19,205
Net revenues	121,557	105,413	101,077
Cost of sales	28,696	27,755	27,664
Selling, general and administrative expenses	35,568	35,624	30,673
Income from operations	57,293	42,034	42,740
Interest income	461	191	182
Net income	$ 57,754	$ 42,225	$ 42,922
Noven s equity in earnings of Novogyne	$ 24,655	$ 17,641	$ 17,094

Table of Contents

The activity in the Investment in Novogyne account for the years ended December 31, 2005, 2004 and 2003 is as follows (in thousands):

	2005	2004	2003
Investment in Novogyne, beginning of year	$ 26,233	$ 28,368	$ 34,684
Equity in earnings of Novogyne	24,655	17,641	17,094
Cash distributions from Novogyne	(26,187)	(18,083)	(21,739)
Non-cash distribution from Novogyne	(1,458)	(1,693)	(1,671)
Investment in Novogyne, end of year	$ 23,243	$ 26,233	$ 28,368

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 $1.5 million tax payment in April 2005, and a $1.7 million tax payment in each of April 2004 and 2003, to the New Jersey Department of Revenue made by Novogyne on Noven s behalf. As discussed in Note 3, such payment was deemed a distribution from Novogyne to Noven.

The condensed Balance Sheets of Novogyne at December 31, 2005 and 2004 are as follows (in thousands):

	2005	2004
Current assets	$ 22,313	$ 25,599
Long-term assets	35,953	39,322
Total assets	58,266	64,921
Allowance for returns	6,168	9,169
Other liabilities	15,286	13,466
Total liabilities (all of which are current)	21,454	22,635
Members capital	$ 36,812	$ 42,286

Table of Contents

The activity for the allowance for returns for the three years ended December 31, 2005 is as follows (in thousands):

Balance December 31, 2002	$ 12,780
Expense related to expired product-current year	3,798
Expense related to expired product-prior year	(2,372)
Expense related to product recalls	6,500
Deductions	(6,466)
Balance December 31, 2003	14,240
Expense related to expired product-current year	8,342
Expense related to expired product-prior year	1,227
Reductions in product recalls expense	(3,345)
Deductions	(11,295)
Balance December 31, 2004	9,169
Expense related to expired product-current year	3,384
Expense related to expired product-prior year	(2,385)
Reductions in product recalls expense	(63)
Deductions	(3,937)
Balance December 31, 2005	$ 6,168

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

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

Table of Contents

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, 2005, 2004 and 2003, Noven had the following transactions with Novogyne (in thousands):

	2005	2004	2003
Revenues:			
Trade product	$ 17,787	$ 15,216	$ 12,411
Sample product and other	2,123	3,582	3,521
Royalties	6,444	5,204	4,978
	$ 26,354	$ 24,002	$ 20,910
Reimbursed expenses:			
Services	$ 20,768	$ 20,014	$ 18,652
Product specific marketing expenses	6,945	7,780	5,608
Reimbursed expenses	$ 27,713	$ 27,794	$ 24,260

As of December 31, 2005 and 2004, the Accounts Receivable Novogyne, net is as follows (in thousands):

	2005	2004
Sales of product	$ 4,126	$ 893
Services provided by Noven	3,835	8,594
Royalty	1,827	1,294
Allowance for product recall		(98)
Deferred profit on Novogyne inventory and other	(876)	(585)
	$ 8,912	$ 10,098

Table of Contents

7. OPERATING AND CAPITAL LEASES:

Noven has various operating and capital leases for computers and equipment. Noven also leases office space and other in close proximity to its manufacturing facility in Miami, Florida.

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 is using 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 is also paying a monthly management fee equal to 1.5% 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 3% during the initial 10-year lease term. After the initial term, the rent will be 95% of the fair market rate of the leased space as determined under the Lease. Noven improved the leased space in order to prepare it for its intended use during 2005. The landlord was responsible for up to approximately $0.9 million of leasehold improvements, which were fully paid in 2005. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements are the responsibility of Noven. For accounting purposes, Noven is amortizing the total 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. Leasehold improvements are recorded at cost and are amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the remaining initial 10-year lease term. Leasehold improvements to the leased space paid by the landlord were recorded by Noven as a deferred rent credit and are being amortized on a straight-line basis over the remaining initial 10-year lease term as a reduction of rent expense. Rent expense related to this lease was $0.4 million for the year ended December 31, 2005.

Lease expense under operating leases, including rent expense related to the Industrial Long-Term Lease described above, was approximately $1.1 million, $0.5 million and $0.3 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Table of Contents

The future minimum rental payments required under noncancelable operating and capital leases as of December 31, 2005 are as follows (in thousands):

	Operating Leases	Capital Leases
2006	$ 843	$ 125
2007	872	
2008	858	
2009	862	
2010	864	
Thereafter	3,658	
Operating lease obligation	$ 7,957	125
Less: portion representing interest		(4)
Capital lease obligation, all current		$ 121

8. INCOME TAXES:

The provision (benefit) for income taxes in 2005, 2004 and 2003 consists of (in thousands):

	2005	2004	2003
Current income taxes:			
Federal	$ 2,347	$ 638	$ 11,516
State	367	150	1,729
	2,714	788	13,245
Deferred income tax (benefit) expense:			
Federal	2,291	4,322	(5,620)
State	275	914	(1,324)
	2,566	5,236	(6,944)
Income tax expense	$ 5,280	$ 6,024	$ 6,301

Table of Contents

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):

	2005	2004
Deferred income tax assets:		
Deferred license revenue	$ 7,732	$ 10,992
Joint venture interest	2,499	2,506
Inventory adjustments and reserves	2,268	2,005
Deferred profit on sales to Novogyne	332	222
Other	467	294
Total deferred income tax assets	13,298	16,019
Deferred income tax liabilities:		
Basis difference in fixed assets	(925)	(1,080)
Net deferred income tax asset	$ 12,373	$ 14,939

Realization of the net deferred income tax asset of $12.4 million and $14.9 million at December 31, 2005 and 2004, 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, 2005 and 2004.

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, 2005, 2004 and 2003, Noven credited $0.3 million, $3.0 million and $0.5 million, respectively, to additional paid-in capital related to the tax benefits from the exercise of stock options.

Table of Contents

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):

	2005		2004		2003	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$ 5,338	35.0	$ 6,037	35.0	$ 6,124	35.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	323	2.1	691	4.0	264	1.5
Extraterritorial income exclusion	122	0.8	(179)	(1.0)	(105)	(0.6)
Research and development expenditures credit	(141)	(0.9)	(135)	(0.8)	(5)	
Increase/(reduction) in IRS audit and state tax contingency accruals	1		(400)	(2.3)	700	4.0
Change in effective deferred tax rate					(700)	(4.0)
Non-taxable interest income	(385)	(2.5)				
Other	22	0.1	10		23	0.1
Income tax expense	$ 5,280	34.6	$ 6,024	34.9	$ 6,301	36.0

Noven is periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. Accordingly, Noven maintains tax contingency accruals for such potential assessments. The accruals are determined based upon Noven s best estimate of possible assessments by the Internal Revenue Service (IRS) or other taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances. The IRS audited Noven s federal income tax returns for the years 2001 through 2003. Noven originally accrued $1.5 million based on its best estimate of possible assessment by the IRS at the time. During 2004, Noven reduced these accruals by $0.4 million based on changing facts and circumstances. During 2005, the IRS completed its audit of those years. In reaching final settlement with the IRS related to these tax years, Noven agreed to certain adjustments, primarily in the areas of research and development credits and to a lesser extent capitalization of software development costs and timing of depreciation and amortization. As a result of the final settlement, Noven reassessed the income tax contingency accruals to reflect the settlement. Based upon this reassessment, Noven recorded a $0.1 million reduction in these accruals during 2005, primarily related to interest charges on potential assessments. In addition, Noven paid the IRS during 2005 for all amounts settled, not including interest charges related to the 2002 and 2003 tax years, as those interest charges were not yet calculated as of December 31, 2005. As of December 31, 2005, Noven had $0.1 million in IRS tax contingency accruals, related to these interest charges, which were paid in January 2006. In addition, Noven accrues for tax contingencies related to tax positions it determines that are more likely than not to be challenged by taxing authorities

Table of Contents

and it believes do not meet the probable criteria of being upheld. As of December 31, 2005, Noven established $0.1 million in tax contingency accruals related to certain state tax positions.

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, 2005, all awards granted under the 1999 Plan are stock options with the exception of unrestricted stock awards for a total of 4,534 shares that were granted in 2004. 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 cannot 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, 2005, there were 3,951,141 stock options issued and outstanding under the 1999 Plan. Historically, the options granted by Noven vest over a period of four or five years, beginning one year after date of grant, and expire seven years after date of grant. As noted in the section Recent Accounting Pronouncements , effective January 1, 2006, Noven adopted SFAS 123(R), which will require compensation expense associated with stock options be recognized in Noven s Statement of Operations, rather than as historically presented as a pro forma footnote disclosure in Noven s financial statements.

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, 2005, there were 52,875 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.

Table of Contents

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

	2005		2004		2003	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	3,739	$ 17.69	3,919	$ 14.51	3,410	$ 15.20
Granted	557	14.25	1,015	21.70	956	10.60
Exercised	(137)	9.52	(769)	8.03	(245)	6.60
Canceled and expired	(155)	24.44	(426)	15.52	(202)	17.17
Outstanding at end of year	4,004	17.23	3,739	17.69	3,919	14.51
Options exercisable at end of year	2,871	19.14	1,541	18.35	1,669	14.78
Shares of common stock reserved	4,504		4,644		4,414	

The following table summarizes information concerning outstanding and exercisable options at December 31, 2005 (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
$5.56 - 5.63	53	0.1	$ 5.61	53	$ 5.61
8.81 - 13.12	1,429	3.9	11.49	789	11.59
13.68 - 19.96	1,269	5.3	15.20	776	16.16
20.56 - 23.00	824	5.9	22.54	824	22.54
31.31 - 41.82	429	1.9	33.53	429	33.53
	4,004			2,871	

On November 6, 2001, Noven s Board of Directors adopted a Stockholder Rights Plan under which Noven declared a dividend of one right for each share of common stock outstanding. Prior to the Distribution Date referred to below, the rights will be evidenced by, and trade with, the certificates for the common stock. After the Distribution Date, Noven will mail rights certificates to the stockholders and the rights will become transferable apart from the common stock. Rights will separate from the common stock and become exercisable

Table of Contents

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 or 2005.

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) Plan 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 $397,000, $353,000 and $274,000 to the 401(k) Plan for the years ended December 31, 2005, 2004 and 2003, respectively.

Table of Contents

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):

	2005	2004	2003
United States	$ 34,546	$ 28,923	$ 22,130
Other countries	17,986	16,968	21,036
Net revenues	$ 52,532	$ 45,891	$ 43,166

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

	2005	2004	2003
Novogyne	$ 26,354	$ 24,002	$ 20,910
Novartis Pharma/Novartis	16,955	14,721	18,829
Endo	6,682	853	
P&G Pharmaceuticals	83	4,371	614
Other	2,458	1,944	2,813
Net revenues	$ 52,532	$ 45,891	$ 43,166

Table of Contents

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

2005	First	Second	Third	Fourth	Full Year
Net revenues[2]	$ 11,736	$ 11,771	$ 12,240	$ 16,785	$ 52,532
Gross profit (loss)(product revenues less cost of products sold)[2,3]	4,256	5,124	(4,969)	1,993	6,404
(Loss) income from operations	(1,086)	(687)	(11,239)	1,367	(11,645)
Equity in earnings of Novogyne[1]	912	8,101	8,081	7,561	24,655
Net income (loss)	$ 211	$ 5,121	$ (1,422)	$ 6,062	$ 9,972
Basic earnings (loss) per share	$ 0.01	$ 0.22	$ (0.06)	$ 0.26	$ 0.42
Diluted earnings (loss) per share	$ 0.01	$ 0.21	$ (0.06)	$ 0.25	$ 0.42

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)[3]	4,061	4,981	3,974	3,341	16,357
(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

[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).

[2] Due to the FDA s determination that Noven s fentanyl ANDA was not approvable, Noven and Endo agreed to terminate the fentanyl portion of the license agreement, as well as the fentanyl supply agreement between the parties, resulting in Noven earning the remaining $5.7 million of previously deferred license revenue, which was recognized in the fourth quarter of 2005. In addition, cost of products sold in the third quarter of 2005 included a $9.5 million charge relating to the write-off of fentanyl inventories and the fourth quarter of 2005 included $0.4 million in charges relating to the destruction of fentanyl inventories.

[3] Gross profit has been revised in all periods to include certain amounts previously included in research and development expenses.

Table of Contents

14. COMMITMENTS AND CONTINGENCIES:

HT STUDIES:

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with use of oral combination 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 Noven s products in the aggregate.

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 commenced a five-year study aimed at determining whether ET use by women aged 40 to 55 reduces the risk of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. While Noven products are not being used in the study, the market for Noven s products could be adversely affected if this study finds that a transdermal estrogen patch is less beneficial than other dosage forms, and Noven could be subject to increased product liability risk if HT patch products are found to increase the risk of adverse health consequences. Noven is currently named as a defendant in one product liability lawsuit involving its HT products and Noven may have liability with respect to other actions in which it has not, to date, been made a party. See Litigation, Claims and Assessment below for a further discussion on related product liability lawsuits.

Table of Contents

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 2003 net revenues by $1.4 million and $6.5 million, 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 was to increase Noven s income before income taxes by $2.2 million in 2004. There are no remaining allowances at Noven or Novogyne related to the 2003 recall.

As a result of the 2003 stability failures, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production. 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. The recall of these lots in the first quarter of 2005 did not have a material impact on Noven s or Novogyne s results of operations because an immaterial number of patches from these lots remained in distribution. Marketing, general and administrative expense in 2004 included an allowance of $0.3 million for estimated costs related to these recalls, which allowance was reduced by $0.2 million during 2005, based on the final close out of the recall. A joint Noven and Novartis task force is working to identify the definitive root cause of the Vivelle-Dot stability failures. Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures relates to certain patch backing material that Noven obtained

Table of Contents

from a raw material supplier. If the root cause determination or additional testing indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. Noven continues to manufacture and ship Vivelle-Dot to Novogyne.

In 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® recall referenced above. Novartis recalled the affected lot. The recall of this lot did not have a material impact on Noven s and Novogyne s financial results in either 2004 or 2005. Noven continues to manufacture and ship CombiPatch® to Novogyne.

In the fourth quarter of 2005, special stability protocols put in place after the October 2004 CombiPatch® stability failure indicated that certain lots of Estalis® (a product substantially similar to CombiPatch® and manufactured for sale outside the United States) did not maintain required specifications throughout the product s shelf-life due to the formation of crystals, resulting in the recall by Novartis Pharma of a total of three commercial lots of Estalis®. Noven is investigating the cause of the stability failure. The recall of these lots did not have a material impact on Noven s financial statements for the year ended December 31, 2005. Noven continues to manufacture and ship Estalis® to Novartis Pharma.

Noven continues to maintain stability testing related to the foregoing production issues. If Noven s testing indicates that additional lots of CombiPatch®, Estalis® or Vivelle-Dot or other products do not meet specifications, there could be additional recalls. Although Noven and Novartis work together in assessing production issues related to these products, the decision to recall product resides with Novartis as the holder of the NDAs for these products and is not within Noven s control. If Noven s estimate concerning product returns associated with the recall are incorrect, or if Noven s continued testing indicates that additional lots are 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. Among other things, any CombiPatch® recalls could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights.

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 our 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

Table of Contents

with the supply agreement s commercial terms. There is no assurance that the agreement s non-commercial terms would be enforceable with respect to post-expiration occurrences. 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:

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual plaintiff in Superior Court of New Jersey Law Division, Atlantic County in which the plaintiff claims personal injury allegedly arising from the use of HT products, including Vivelle®. The plaintiff claims compensatory, punitive and other damages in an unspecified amount. Noven does not expect any activity in this case in the near future, as the court has indicated that it intends to stay proceedings in all its pending and future HT cases except for cases where Wyeth Pharmaceuticals and its affiliates and Pfizer, Inc. are the defendants.

Novartis has advised Noven that Novartis has been named as a defendant in at least 16 pending additional lawsuits that include approximately 21 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 our Vivelle-Dot, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the one referenced above. 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 $4.9 million with an offsetting insurance recovery of $3.5 million. This accrual represents Novartis management s best estimate as of December 31, 2005. The outcome of these product liability lawsuits cannot ultimately be predicted.

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

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.

Table of Contents

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 subject to a one-year extension unless otherwise terminated by the parties.

Noven has a formula bonus plan that includes company and individual performance goals. Noven incurred $3.6 million, $3.8 million and $2.8 million of bonus expenses in 2005, 2004 and 2003, 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 2005, 2004 and 2003, Noven met or exceeded the Plan s performance goals, and in accordance with the plan formula the bonus awards to most employees were greater than their initial target awards.

Table of Contents

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, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 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.

March 6, 2006

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Balance Sheets
December 31, 2005 and 2004

	2005	2004
Assets		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation	$ 17,951,634	$ 23,131,128
Finished goods inventory (net of reserves of $31,977 and $0 as of December 31, 2005 and 2004)	4,053,734	2,177,436
Other current assets	307,475	290,499
Total current assets	22,312,843	25,599,063
Long-term assets		
Insurance receivable (Note 7)	3,510,868	700,000
Intangible assets (Note 3) (net of amortization of $29,352,458 and $23,172,993 as of December 31, 2005 and 2004)	32,442,187	38,621,652
Total long-term assets	35,953,055	39,321,652
Total assets	$ 58,265,898	$ 64,920,715
Liabilities and Members Capital		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc. (Note 6)	$ 9,787,307	$ 10,682,732
Accrued liabilities	554,342	1,182,936
Product liability reserve (Note 7)	4,944,815	1,600,000
Allowance for returns (Note 4)	6,167,605	9,168,856
Total current liabilities	21,454,069	22,634,524
Commitments and contingencies (Note 7)		
Members capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	3,953,920	9,428,282
Total members capital	36,811,829	42,286,191
Total liabilities and members capital	$ 58,265,898	$ 64,920,715

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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Operations
Years Ended December 31, 2005, 2004 and 2003

	2005	2004	2003
Net sales			
Third parties	$ 119,331,180	$ 101,834,528	$ 98,572,264
Novartis Pharmaceuticals Canada, Inc.	2,226,126	3,578,932	2,505,148
	121,557,306	105,413,460	101,077,412
Cost of sales			
Sales to third parties	15,148,711	14,882,911	15,454,422
Sales to Novartis Pharmaceuticals Canada, Inc.	923,604	1,489,292	1,052,221
Noven royalties	6,444,033	5,203,932	4,978,247
Amortization of license/marketing rights	6,179,465	6,179,465	6,179,465
	28,695,813	27,755,600	27,664,355
Gross profit	92,861,493	77,657,860	73,413,057
Operating expenses			
Sales and marketing expenses	31,657,682	31,364,085	28,019,902
Administrative expenses	3,377,400	3,359,684	2,652,908
Product liability expenses, net of insurance receivable	533,947	900,000	
Income from operations	57,292,464	42,034,091	42,740,247
Other income			
Interest income	461,294	191,287	181,957
Net income	$ 57,753,758	$ 42,225,378	$ 42,922,204

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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Members Capital
Years Ended December 31, 2005, 2004 and 2003

	Total
Members capital at January 1, 2003	$ 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
Net income	57,753,758
Distributions to Novartis	(35,583,169)
Distributions to Noven	(27,644,951)
Members capital at December 31, 2005	$ 36,811,829

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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Cash Flows
Years Ended December 31, 2005, 2004 and 2003

	2005	2004	2003
Cash flows from operating activities			
Net income	$ 57,753,758	$ 42,225,378	$ 42,922,204
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	31,977		(26,487)
Changes in assets and liabilities			
Decrease (increase) in due from affiliate Novartis Pharmaceuticals Corporation	5,179,494	(1,798,501)	7,138,185
Decrease (increase) in due from affiliate Novartis Pharmaceuticals Canada, Inc.		696,620	(696,620)
(Increase) decrease in finished goods inventory	(1,908,275)	504,677	3,659,656
Increase in other current assets	(16,976)	(24,978)	(224,131)
Increase in insurance receivable	(2,810,868)	(700,000)	
(Decrease) increase in due to affiliate Noven Pharmaceuticals, Inc.	(895,425)	3,518,108	2,599,345
(Decrease) increase in accrued liabilities	(628,594)	1,009,686	50,867
Increase in product liability reserve	3,344,815	1,600,000	
(Decrease) increase in allowance for returns	(3,001,251)	(5,071,425)	1,460,275
Net cash provided by operating activities	63,228,120	48,139,030	63,062,759
Cash flows from financing activities			
Distributions to members (Note 5)	(63,228,120)	(48,139,030)	(63,062,759)
Net cash used in financing activities	(63,228,120)	(48,139,030)	(63,062,759)
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.

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

1. Organization and Business

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 does not have any employees. The Company relies on Novartis and Noven to perform all services (Note 5 and 6).

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 sanofi-aventis as successor in interest of Aventis Pharmaceuticals (sanofi-aventis) (Note 3).

2. Summary of Significant Accounting Policies

Basis of Presentation

The preparation of the financial statements are in conformity with accounting principles generally accepted in the United States of America.

Use of Estimates

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

The preparation of financial statements require the use of estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant assumptions are employed in estimates used in the deductions from gross sales for allowances, returns, and discounts, provisions for product liability, anticipated recovery of insurance related receivables, and assumptions for cash flows when testing assets for impairment. Actual results could differ from the estimated results.

Cash and Cash Equivalents

The Company does not have cash accounts. Novartis administers cash collections and disbursements on behalf of the Company. The statement of cash flows for the year ended December 31, 2005, 2004, and 2003 are based on the cash accounts Novartis administers on behalf of the Company.

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

The Company recognizes revenue when all the risks and rewards of ownership have transferred to the customer, which occurs at the time of shipment of products. Revenues are reduced at the time of sale to reflect expected returns that are estimated based on historical experience. Additionally, provisions are made at the time of sale for all discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenue.

Sales Allowances

Novartis records the Company s sales net of sales allowances for chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances that are established in the same period the related revenue is recognized, resulting in a reduction to sales and the Due from affiliate Novartis. Novartis maintains the reserves associated with such sales allowances on behalf of the Company, excluding the sales returns accrual that is maintained and recorded by the Company. Novartis is responsible for paying rebates and processing returns on behalf of the Company. 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.

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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,		
	2005	**2004**	**2003**
Gross sales	$ 134,675,279	$ 121,212,227	$ 117,776,888
Sales returns	935,912	6,224,072	7,925,829
Managed health care rebates	8,018,050	7,898,343	6,574,981
Cash discounts	2,690,058	2,425,331	2,362,639
Medicaid and Medicare rebates including prescription drug savings cards	938,423	1,340,483	949,715
Chargebacks	969,492	860,412	838,245
Other discounts	1,792,164	629,058	553,215
Total sales allowances	15,344,099	19,377,699	19,204,624
Net sales to third parties	$ 119,331,180	$ 101,834,528	$ 98,572,264

Advertising Costs

Advertising costs are expensed as incurred.

Shipping and Handling Costs

The Company does not charge customers for shipping and handling costs. Shipping and handling costs are included in sales and marketing expenses and were $146,322, $118,936, $116,148 for 2005, 2004, and 2003 respectively.

Income Taxes

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

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 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.

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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 sanofi-aventis. The transactions were structured as (a) a direct purchase by the Company from sanofi-aventis of the sales and marketing rights and inventory for $25,000,000 which was paid at closing, (b) a grant-back by sanofi-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 sanofi-aventis, and by the Company to Noven, was $40,000,000, which was due and paid. The Company 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, which is the estimated useful life. The accumulated amortization for this intangible asset was $29,352,458 and $23,172,993 as of December 31, 2005 and 2004. Amortization expense is $6,179,465 per year. In 2005, the Company revised the presentation of amortization expense to include this item within cost of sales. The presentation for 2003 and 2004 was revised to conform with 2005.

The HT studies (Note 7) led to a triggering event and as such, the Company completed an impairment test of the intangible asset using projected undiscounted net cash flows applicable to CombiPatch®. Based on this test, the Company determined that there is no impairment. Further, evaluations may be required if additional declines in the market for CombiPatch® develop due to the HT studies or other factors.

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.

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

The activity for the allowances for returns, including product recalls, for the three years ended December 31, 2005 is as follows:

Balance January 1, 2003	$ 12,780,006
Current year provision	10,297,350
Prior year adjustment	(2,371,521)
Deduction-returns processed	(6,465,554)
Balance December 31, 2003	14,240,281
Current year provision	4,997,001
Prior year adjustment	1,227,071
Deduction-returns processed	(11,295,497)
Balance December 31, 2004	9,168,856
Current year provision	3,320,440
Prior year adjustment	(2,384,528)
Deduction-returns processed	(3,937,163)
Balance December 31, 2005	$ 6,167,605

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. There are no remaining allowances for the 2003 recalls as of December 31, 2005 and 2004.

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 remained in distribution. The effect of these recalled lots to the Company s results of operations was immaterial. The final field alert for the recall of the additional lots of Vivelle-Dot was submitted to the FDA on March 11, 2005. The FDA did not take action with respect this recall of Vivelle-Dot .

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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. 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 or 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 . The Company s results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

In October 2004, Noven s product stability testing program indicated that one commercial lot of the 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 recalled the affected lot. The recall of this lot did not have a material impact on the Company s financial results in either 2005 or 2004. Noven continues to manufacture and ship CombiPatch® to the Company.

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:

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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

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

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

Lastly, all remaining net income attributable to Vivelle® and all other net income, including 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 2005 distributions to Novartis and Noven of $35,583,169 and $27,644,951, respectively, are payments related to New Jersey state taxes of $2,076,945 and $1,458,356, respectively. Included in the 2004 distributions to Novartis and Noven of $28,363,294 and $19,775,736, respectively, are payments to New Jersey for 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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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.

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, 2005, 2004 and 2003, Novartis charged the Company $3,133,136, $2,796,760 and $3,205,708, respectively, for these services.

Bookkeeping, Accounting and Treasury

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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 affiliate Novartis. The balances in this account of $17,951,634, $23,131,128 and $21,332,627 as of December 31, 2005, 2004 and 2003, 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, 2005, 2004 and 2003 at an average annual rate of 3.6%, 1.4% and 1.2%, respectively. During these periods, interest of $461,294, $191,287 and $181,957, respectively, was earned and is reflected in the amount Due from affiliate 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 affiliate Novartis.

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

	Years Ended December 31,	
	2005	**2004**
Balance at the beginning of the period	$ 23,131,128	$ 21,332,627
Net sales third parties (excluding returns)	120,267,092	108,058,600
Sales returns processed	(3,937,163)	(11,295,497)
Copromotion income		945,000
Interest income on cash balances	461,294	191,287
Distributions to members	(63,228,120)	(48,139,030)
Payment to Noven for marketing services, inventory purchases and royalties	(55,134,309)	(48,114,238)
Disbursements made on behalf of the Company	(2,752,411)	(1,209,814)
Novartis service charges	(3,133,136)	(2,796,760)
Cash received from Novartis Canada	2,226,126	4,262,142
Other	51,133	(103,189)
Total	$ 17,951,634	$ 23,131,128

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

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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

During the years ended December 31, 2005, 2004 and 2003, Noven charged the Company $20,768,126, $20,014,190 and $18,652,109, 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, 2005, 2004 and 2003 were $8,970,238, $10,663,298 and $8,835,488, 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. Included in the cost of sales are royalty expenses of $6,444,033, $5,203,932, and $4,978,247 for the years ended December 31, 2005, 2004, and 2003 respectively.

Inventory Purchases

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, 2005, 2004 and 2003, the Company purchased products from Noven in the amounts of $17,787,186, $15,216,288 and $12,410,859, 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,	
	2005	**2004**
Purchases of inventory	$ 4,125,516	$ 794,745
Services provided by Noven	3,835,010	8,594,065
Royalties	1,826,781	1,293,922
	$ 9,787,307	$ 10,682,732

7. Commitments and Contingencies

Litigation, Claims and Assessments

As of December 31, 2005, there are 21 lawsuits that include 32 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®. Of the 21 lawsuits filed, 2 lawsuits have been dismissed and 1 lawsuit has been settled for a nominal amount. For the remaining 18 pending lawsuits, the Company has been named in 2 lawsuits, 1 of which also names Noven and Novartis, and the remaining 16 lawsuits name only Novartis.

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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

may 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 $4,944,815 as of December 31, 2005 for expected defense and settlement expenses related the 18 pending lawsuits 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 including that of Novartis.

To the extent insurance coverage provides for recovery of claims, the Company has recorded an insurance receivable, using estimates consistent with those used to develop the liability. The Company recorded an insurance receivable of $3,510,868 as of December 31, 2005. At this time, the Company s insurance carrier has not denied coverage of these claims.

The Company, 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 operations 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 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.

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 above) would not apply for occurrences prior to policy expiration, but reported within the extended reporting period of 5 years.

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

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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. As of December 31, 2005, Noven has incurred a nominal amount of development costs for this next generation estrogen patch.

The Company has a supply agreement with Noven for the purchase of the Vivelle® and Vivelle-Dot products which 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.

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 are more or less beneficial than an oral HT product. Although the Company s Vivelle-Dot product is not being used in the study, among other risks related to this study, the market for Vivelle-Dot would likely be adversely affected if this study finds that a 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 HT patch products are found to increase the risk of adverse health consequences.

Table of Contents

Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2005

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.

8. Significant Concentrations

The Company considers there to be a concentration risk for all customers that represent 10% or more of the Company s total sales. Sales to the Company s top three distributors accounted for 35%, 37% and 21% in 2005, 40%, 24% and 20% in 2004, and 45%, 23% and 21% in 2003.