

NOVEN PHARMACEUTICALS INC

Form 10-K

March 12, 2007

**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, 2006**  
**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. 144<sup>th</sup> Street, Miami, Florida 33186  
305-253-5099**

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value \$.0001

Name of exchange on which registered: Nasdaq Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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  No

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  No

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

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  Accelerated filer  Non-accelerated filer

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

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant was approximately \$421 million (computed by reference to the price at which the common equity was last sold on June 30, 2006, the last business day of the registrant's most recently completed second fiscal quarter).

As of March 1, 2007, there were 24,759,369 shares of Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Part III: Portions of registrant's Proxy Statement for its 2007 Annual Meeting of Shareholders.

**NOVEN PHARMACEUTICALS, INC.**  
**Annual Report on Form 10-K**  
**for the year ended December 31, 2006**  
**TABLE OF CONTENTS**

	<b>Page</b>
<u><b>PART I</b></u>	
<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	21
<u>Item 1B. Unresolved Staff Comments</u>	36
<u>Item 2. Properties</u>	36
<u>Item 3. Legal Proceedings</u>	37
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	38
<u><b>PART II</b></u>	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	40
<u>Item 6. Selected Financial Data</u>	42
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	43
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	73
<u>Item 8. Financial Statements and Supplementary Data</u>	73
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	73
<u>Item 9A. Controls and Procedures</u>	73
<u>Item 9B. Other Information</u>	78
<u><b>PART III</b></u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	78
<u>Item 11. Executive Compensation</u>	78
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	78
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	78
<u>Item 14. Principal Accounting Fees and Services</u>	78
<u><b>PART IV</b></u>	
<u>Item 15. Exhibits, Financial Statement Schedules</u>	78
<u>EX-11 Computation of Earnings Per Share</u>	
<u>EX-21 Subsidiaries</u>	
<u>EX-23.1 Consent of Deloitte &amp; Touche LLP</u>	
<u>EX-23.2 Consent of PricewaterhouseCoopers LLP</u>	
<u>EX-31.1 Section 302 Certification of CEO</u>	
<u>EX-31.2 Section 302 Certification of CFO</u>	
<u>EX-32.1 Section 906 Certification of CEO</u>	
<u>EX-32.2 Section 906 Certification of CFO</u>	

**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 the treatment of Attention Deficit Hyperactivity Disorder ( ADHD ) and in menopausal hormone therapy ( HT ). These products include:

Daytrana (methylphenidate transdermal system), the first and only transdermal patch approved by the United States Food and Drug Administration ( FDA ) for the treatment of ADHD.

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

**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 ADHD and HT) through strategic collaborations and new product development. Products under development may include 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 established development collaborations with Shire plc ( Shire ), Endo Pharmaceuticals Inc. ( Endo ) and other companies relating to the development of new transdermal products using our technologies.

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.

We were incorporated in Delaware in 1987 as Noven Pharmaceuticals, Inc., and our principal executive offices are located at 11960 S.W. 144<sup>th</sup> Street, Miami, Florida 33186; our telephone number is (305) 253-5099 and our Internet website address is [www.noven.com](http://www.noven.com).

**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 the remaining 51% equity interest. The joint venture company is a Delaware limited liability company which is legally known as Vivelle Ventures LLC, but which does business under the Novogyne name. We account for our interest in Novogyne using the equity method. For the past several years, 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 48% share of monthly total prescriptions written in the United States as of December 2006.

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 Vivelle® and Vivelle-Dot®. 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. In January 2006, the Novogyne sales force, formerly a contract sales force, became direct employees of Noven. As is the case with other costs incurred by us on behalf of Novogyne, we are reimbursed by Novogyne for costs associated with these sales force employees.

**Table of Contents**

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. In the years 2006, 2005 and 2004, Novogyne made cash distributions of \$26.4 million, \$26.2 million and \$18.1 million, respectively, to Noven. The amount of cash we receive from Novogyne in any period may not be the same as the amount of income we recognize from Novogyne for that period.

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 percentage share of income after Novartis' preferred return increases as product sales increase, subject to a maximum of 49%. In 2006, 2005 and 2004, our equity in earnings of Novogyne, as reflected in our statements of operations, was \$28.6 million, \$24.7 million, and \$17.6 million, respectively, representing 48.4%, 47.7% and 48.8% of Novogyne's income after Novartis' preferred returns for each of those years.

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 Vivelles-Dot® and Vivelles® 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 we are the purchaser, then we must also pay an additional amount equal to the net present value of Novartis' preferred 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 than us, and therefore may be in a better position to be the purchaser if the buy/sell 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 technologies to further our leadership position in the transdermal drug delivery field. This strategy includes:

**Table of Contents**

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 delivery 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 (developed internally and/or acquired) 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.

Our strategy also includes continued internal efforts to improve production efficiencies and facility utilization in order to improve the overall profitability of our manufacturing operations.

In pursuing our strategy, we intend to focus on developing products in a range of therapeutic areas, including ADHD, hormone therapy, central nervous system conditions such as pain management, and other areas where we believe transdermal therapies may be beneficial. 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 attractive financial returns. 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 these strategies in light of evolving business, industry, market and other conditions. No assurance can be given that we will implement all or any part of our business or growth strategies, that our strategies may not change from time to time or that any strategy we adopt will be successful.

**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<sup>®</sup> patch technology. DOT Matrix<sup>®</sup> 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

**Table of Contents**

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<sup>®</sup> technology may also permit us to develop patient-friendly patches in cases where, due to the nature of the compound or the size of the required daily dose, competitors' products would not be able to deliver a therapeutic dose without making the patch objectionably large.

Patches incorporating our DOT Matrix<sup>®</sup> technology, such as Daytrana, Vivelle-Dot<sup>®</sup>, and CombiPatch<sup>®</sup>, are diffusion-based patches that 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.

**ADHD Therapy**

We have developed a once-daily transdermal methylphenidate patch called Daytrana for the treatment of ADHD. Daytrana is the first and only transdermal medication approved to treat the symptoms of ADHD, and is approved for children aged six to twelve years. Shire, the market leader in this therapeutic category, is the exclusive, global licensee of Daytrana. The FDA approved Daytrana in April 2006. The product combines the active ingredient methylphenidate with our DOT Matrix<sup>®</sup> technology, and is designed to provide continuous release of medication throughout the day.

ADHD is characterized by developmentally inappropriate levels of attention, concentration, activity, distractibility, hyperactivity 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 (other than Daytrana) 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 class for the treatment of ADHD. We believe that Daytrana provides physicians and parents with broad dosing flexibility, in that dosing can be discontinued by simply removing the patch if a shorter duration of effect is desired or if late-day methylphenidate side effects appear, and may offer other advantages as compared to certain oral ADHD medications.

In 2003, we licensed to Shire the exclusive global rights to market Daytrana for payments by Shire of up to \$150.0 million and ongoing manufacturing revenues. In consideration for the transaction Shire agreed to pay us as follows: (i) \$25.0 million was paid upon closing of the transaction in April 2003; (ii) \$50.0 million was paid in April 2006 upon receipt of final marketing approval by the FDA; and (iii) three installments of \$25.0 million each are payable upon Shire's



**Table of Contents**

achievement of \$25.0 million, \$50.0 million and \$75.0 million in annual Daytrana net sales, respectively. For purposes of the sales milestones, Shire's annual net sales are measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first calendar quarter during which trailing 12-month sales exceed the applicable threshold. We are currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013. During 2006, we recognized \$5.9 million in license revenues related to the Shire collaboration. Shire's net sales of Daytrana exceeded the threshold for the first sales milestone in the fourth quarter of 2006 and, accordingly, we received a \$25 million payment from Shire in the first quarter of 2007.

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 sales milestones. Additionally, Shire is required to use reasonable commercial efforts to maximize Daytrana product sales, and actively promote Daytrana as a strategic product within Shire's ADHD portfolio, until payment of all sales milestones. Upon the closing date in April 2003, we also entered into a long-term supply agreement under which we manufacture and supply Daytrana to Shire at a fixed price. In 2006, our product sales of Daytrana to Shire were \$8.6 million. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from that source. If Shire were to exercise this right, our revenues and profits from sales of Daytrana would be adversely affected.

In June 2004, we entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD. The product entered Phase I clinical development in December 2006. Our amphetamine patch project is discussed in additional detail under "Development Collaborations" below.

**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 \$42.7 million, \$43.8 million and \$39.8 million for 2006, 2005 and 2004, respectively, which represented 70%, 83% and 87% of our revenues in each of those years.

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

**Table of Contents**

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, and statistical analysis announced in December 2006 indicated a drop in breast cancer cases since the publication of the WHI study. 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 our prescription rates, see Management's Discussion and Analysis of Financial Condition and Results of Operations Overview of Noven and our Novogyne Joint Venture.

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 42 to 58 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. Noven's products have been named in lawsuits filed against Noven, Novogyne and Novartis. See Item 3 Legal Proceedings.

*Advanced Transdermal Estrogen Patch*

Utilizing our proprietary DOT Matrix<sup>®</sup> technology, our advanced transdermal estrogen patch (marketed as Vivelle-Dot<sup>®</sup> and Estradot<sup>®</sup>) is one-third the area of our original Vivelle<sup>®</sup> 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<sup>®</sup> is the most prescribed transdermal ET product in the United States. This product is currently available in the United States in five dosage strengths. The lowest dosage

**Table of Contents**

strength is approved only for prevention of 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. In Canada, Vivelle-Dot® is marketed as Estradot® by an affiliate of Novartis Pharma AG ( Novartis Pharma ). Novartis Pharma holds the rights to market this product 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. Sanofi-aventis ( Aventis ) has marketing rights for Vivelle-Dot® in Japan.

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. 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 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®.

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 the Estradot® product is a long-term agreement. The supply agreement for Vivelle-Dot® and Vivelle® expired in January 2003. Since the expiration of this agreement, the parties have continued to operate in accordance with its 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 favorable business terms with Novartis or resolve any dispute between us 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

**Table of Contents**

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 territories where our advanced Vivelle-Dot® ET patch has gained acceptance. We ceased manufacturing of Vivelle® for the United States market at 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 commercial terms of 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.

Pursuant to license and long-term supply agreements with Novartis Pharma, we manufacture the combination product for Novartis Pharma 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.

**Table of Contents**

**Development Collaborations**

*Shire*

In addition to our agreements with Shire related to Daytrana, in June 2004 we entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD, and in July 2006, we amended this agreement with Shire. Under the amended agreement, Shire paid us a non-refundable \$1.0 million in August 2006 in exchange for the option of purchasing, for an additional \$5.9 million, the exclusive developmental rights to the product. The amended agreement further provides that we will perform certain early-stage development activities which were previously to be performed by Shire. Upon our completion of such development activities, Shire has the option to pay us the \$5.9 million to continue exclusive development of the product. If Shire does not exercise this option, rights to further develop the product will revert to us. The product entered Phase I clinical development by us in December 2006. The \$1.0 million was included in deferred contract revenues on our balance sheet as of December 31, 2006.

*P&G Pharmaceuticals*

In April 2003, we established a collaboration with Procter & Gamble Pharmaceuticals, Inc. ( P&G Pharmaceuticals ) for the development of new prescription 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. In the U.S., P&G Pharmaceuticals withdrew its New Drug Application ( NDA ) for Intrinsa in December 2004 based on safety concerns expressed by an FDA Advisory Committee and other factors. P&G Pharmaceuticals has indicated that work on Intrinsa for the U.S. market has been placed on hold while they evaluate alternatives for the project. If P&G Pharmaceuticals is unable to identify a practical strategy to complete development and commercialize the product in the U.S., or if their evaluation of alternatives significantly delays the project, the prospects for our collaboration with P&G Pharmaceuticals will be adversely affected.

*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 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's decision to proceed with the fentanyl project is expected to depend upon, among other things, the expense, timeline and risk of seeking FDA approval, and the size and sustainability of the United States market opportunity at the time our product would be launched. For a discussion of the effects of the FDA's review of our ANDA, see Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations.

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 development activities being conducted in connection with our Endo and Shire collaborations, we entered into three development collaborations in 2005 and have entered into a number of early stage feasibility and/or development agreements with other pharmaceutical companies to determine the feasibility of transdermal delivery of various compounds.

For the years ended December 31, 2006, 2005 and 2004, we spent \$11.5 million, \$13.2 million and \$9.5 million, respectively, for research and development activities, which does not include amounts expended on additional clinical studies for Daytrana in 2004 and 2005 because those amounts were reimbursements to Shire and were recorded as a reduction of a portion of the \$25.0 million non-refundable deferred license revenue 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.

Our long-term strategy is dependent upon the successful development of new products and their successful commercialization. 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 are beyond our control, 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.

**Table of Contents**

**Competition**

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

Competition in drug delivery systems is generally based on a company's marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. As a general matter, transdermal drug delivery systems are more expensive and difficult 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 Daytrana, Vivelite-Dot<sup>®</sup> 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.

Daytrana participates in a highly competitive market for the treatment of ADHD, 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 February 2007 received marketing approval for an amphetamine pro drug for the treatment of ADHD. We cannot assure that Shire will continue to market Daytrana aggressively or effectively, 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 ).

In the market for HT products, Novogyne competes against Wyeth Pharmaceuticals, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Berlex Laboratories, Esprit Pharma, Inc., Ascend Therapeutics, Inc., Barr Laboratories and others, including Novartis, Novartis Pharma and their affiliates. We expect increased competition in the HT market as new and innovative products continue to be introduced in this field, including products using alternative delivery systems such as gels and creams, lower-dosage products, and products that may be used to treat menopause-related symptoms that are not hormone-based or that may reduce the risks related to hormone-based products. 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.

**Table of Contents**

**Dependence on Licensees and Joint Venture**

During 2006, 44%, 25%, and 24% of our revenues were attributable to Novogyne, Novartis Pharma (and its affiliates) and Shire, respectively, and substantially all of our income before income taxes was attributable to our equity in Novogyne's earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novartis Pharma, Novogyne, 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<sup>®</sup>, Vivelle<sup>®</sup> and CombiPatch<sup>®</sup> 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 Shire require Shire to use reasonable commercial efforts to market Daytrana, until payment of all milestone payments, but Shire has no obligation to continue marketing Daytrana thereafter. While our agreements with our marketing partners may impose certain obligations on them, 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.

**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. 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 products under development is ultimately not obtained or if such products are not successfully commercialized, we may be unable to fully recover our up-front costs to expand our manufacturing capabilities. For products under development, unless our partner is responsible for pre-launch inventories, we may be unable to 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



**Table of Contents**

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 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.

**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<sup>®</sup>, we have historically granted product marketing rights to other pharmaceutical companies.

Our strategy, however, includes the possibility that we may retain the rights to a particular new product and develop, market and sell it ourselves. We may also seek to commercialize products ourselves through the acquisition of one or more products or the acquisition of a company with marketed or marketable products. A decision to commercialize a product ourselves 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 any clinical studies, sales, marketing and distribution. A decision to develop and commercialize products ourselves could result in substantial research, development, sales, marketing and acquisition 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 we have responsibility for the day-to-day management of Novogyne's marketing efforts and sales force. Effective January 2006, the Novogyne sales force, formerly a contract sales force, became direct employees of Noven. As is the case with other costs incurred by us on behalf of Novogyne, we are 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<sup>®</sup> 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.

## **Table of Contents**

### **Patents and Proprietary Rights**

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained 35 United States patents and over 315 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 154 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) and Vivelle-Dot® are registered trademarks of Novartis AG;
- CombiPatch® and Estalis® (U.S.) are registered trademarks of Vivelle Ventures LLC;
- Menorest is a trademark of Novartis AG;
- Femiest® is a registered trademark of Aventis in Japan;

**Table of Contents**

- Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited;
- Concerta® is a registered trademark of ALZA Corporation;
- Intrinsa is a trademark of P&G Pharmaceuticals;
- Vioxx® is a registered trademark of Merck & Co., Inc.;
- Duragesic® is a registered trademark of Johnson & Johnson Corporation;
- Ortho Evra® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.;
- Vyvanse is a trademark of Shire LLC.

**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 guarantee 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, 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 or make product improvements 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

**Table of Contents**

patent or that such patent is invalid, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act ), the FDA may not finally approve the ANDA until the 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 and dosage strength 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. Phase IV trials may be required 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 subjects.

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

**Table of Contents**

notification may be required to be submitted to the FDA and FDA approval required prior to implementation of the change.

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. For example, the approval letter for Daytrana requires post-marketing surveillance and post-marketing studies relating to the possibility of skin sensitization.

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.

**Table of Contents**

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, 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**

We had no material backlogs as of March 1, 2007 and March 1, 2006.

**Employees**

As of December 31, 2006, we had approximately 518 employees, approximately 259 of which were engaged in manufacturing, process development, quality assurance and quality control, 28 in research and development, 10 in clinical research and regulatory affairs, and 221 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 in January 2006, increasing the number of Noven employees by approximately 120 individuals.

**Seasonality**

Although our business is affected by the purchasing patterns of our partners and wholesale drug distributors, there are no significant seasonal aspects to our existing business at this time. We may experience some seasonality in the future with respect to our sales of Daytrana to Shire as ADHD products are generally prescribed more frequently during the school year than during the summer months.

**Available Information**

Our Internet website address is [www.noven.com](http://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 Securities and Exchange Commission (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

**Table of Contents**

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 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 and to a lesser extent, Daytrana. 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 55% from the second quarter of 2002 (the quarter immediately preceding the WHI study) to the fourth quarter of 2006. In addition, a private foundation has commenced a five-year study aimed at determining whether ET use by women aged 42 to 58 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, ongoing FDA inquiries into the possible cardiac, psychiatric and other side effects of ADHD medications have led the FDA to require distribution of patient medication guides when ADHD medications are dispensed, and may lead the FDA to require the addition of related "black-box" warnings to the labeling of ADHD medications. 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.**

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 is 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 or at all. 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, 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 product 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 product base through the acquisition of other companies, the acquisition of rights to products, or through the license or purchase of rights to new 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. We may undertake an acquisition that initially results in dilution to our earnings per share. 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<sup>®</sup>, and for selling Novogyne's products to its trade customers. For Daytranawe have granted the exclusive marketing rights to Shire. Failure of Novartis, Shire or 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 in February 2007 received marketing approval for an amphetamine pro drug for the treatment of ADHD. Shire is likely to dedicate substantial resources to the promotion of this product, which is expected to reduce the level of promotion related to Daytrana. In addition, Shire is only contractually obligated to use reasonable commercial efforts to market Daytrana until payment of all sales milestones and has no obligation to continue marketing Daytrana thereafter. 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 2006, and Novogyne's results will likely continue to be material to us in the future. Because, among other things, we are much smaller than 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 than us, and therefore may be in a better position to be the purchaser if the provision is triggered. If the buy/sell 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 be able to adequately perform the services currently being provided by Novartis or that we would not be adversely affected

**Table of Contents**

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 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 agreements 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 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 is expensive and may take several years. The process is subject to the broad authority and discretion of the FDA.

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 or require that any such new products be subject to more extensive or more rigorous study and testing prior to being approved, or be subject to more extensive conditions or limitations after approval.

As a result of the publicity surrounding COX-2 inhibitors, certain antidepressants, and the publicity surrounding HT products, 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.

**Table of Contents**

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 formulations. 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 Daytrana, 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.

The market for Daytrana may be negatively affected by a number of factors. We have received reports concerning difficulty removing the release liner from a small percentage of Daytrana patches. Although the product meets specifications, during the first quarter of 2007, we implemented enhancements intended to make Daytrana easier to use. If Daytrana sales are materially impacted because of this issue, then Noven's results of operations and financial condition would likely be adversely affected. Further, the market for Daytrana could be negatively affected by the outcome of ongoing FDA inquiries into the possible cardiac, psychiatric and other side effects of ADHD medications which may lead the FDA to require the addition of related black-box warnings to the labeling of ADHD medications, any negative results from the post-marketing studies and surveillance that the FDA required in connection with its approval of Daytrana, as well as ongoing public debate in the United States regarding the appropriateness of using methylphenidate and other medications to treat children with ADHD. 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 for Daytrana. 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.

**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 with Novogyne 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 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

## **Table of Contents**

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 as is the case for our lead products, Vivelle-Dot® and Daytrana), 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. As a general matter, the manufacture of transdermal delivery systems is more complex than for oral products, and special handling of the product may be required after shipment by Noven, which may increase the risk of a recall of one of our products. We have experienced a number of production issues, some of which have led to recalls in the past. 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 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.**

Inefficiencies and other scale-up problems can occur in the process of manufacturing a new product 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

**Table of Contents**

launches, revenues and product gross margins could be adversely affected. Significant scale-up or other manufacturing problems could also result in our collaboration partners, if permitted under our agreements, 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. If we experience manufacturing difficulties such as quality problems, yield deficiencies or similar issues, our overall manufacturing costs may be higher than anticipated.

**If we are unable to improve our margins on Daytrana our results of operations will be adversely affected.**

The price at which we sell Daytrana to Shire is determined in accordance with the terms of our Toll Conversion and Supply Agreement with Shire. Because the price at which we sell Daytrana to Shire is generally fixed, our margin on sales of Daytrana is determined by the production costs we incur to produce the product. During the initial commercial production of Daytrana during 2006, our gross margin on that product was negative (i.e. the costs we incurred to produce the product were greater than the revenue we realized from the sales of that product). The negative gross margin resulted primarily from start-up expenses associated with the production of Daytrana, and production inefficiencies including lower than desired yields and increased costs associated with meeting launch timelines. Although our gross margins on sales of this product began to improve in the third quarter of 2006, if we are unable to continue to improve production yields and reduce our costs of production for Daytrana, we will be unable to further improve our margin on sales of the product and our operating results will be adversely affected. Our ability to produce Daytrana and improve the gross margins from the sale of this product is contingent on, among other things, receiving a sufficient supply of the active methylphenidate ingredient from Shire as well as sufficient quota from the DEA for this controlled substance. At any given time, we expect to have applications pending with the DEA for annual or additional procurement quota that may be critical to continued production. Any delay or stoppage in the supply of the active methylphenidate ingredient could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations.

**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.

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

**Table of Contents**

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.

**Our supply of methylphenidate and other controlled substances must be approved by the DEA.**

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. Similarly, the manufacturers who supply the controlled substances to us must also receive authorization from the DEA to manufacture the substances. We cannot assure that we or our suppliers will be granted sufficient DEA quota to meet our production requirements for controlled substances. Previous grants of methylphenidate quota for Daytrana have been less than originally requested and we have had to re-apply for additional quota. We expect that this application and re-application process will continue with respect to future grants. We cannot guarantee that the timing or quantity of future DEA awards of methylphenidate quota will be sufficient for us to meet our production requirements for Daytrana, and the timing and quantity of any future award may impact our production costs and market penetration of Daytrana.

**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.

We face continued competition in the HT market as new and innovative products continue to be introduced in this field, including products using alternative delivery systems such as gels and creams, lower-dosage products, and products that may be used to treat menopause-related symptoms that are not hormone-based or that may reduce the risks related to hormone-based products.

The ADHD market is highly 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, and Lilly. Johnson & Johnson markets Concerta®, the market-leading methylphenidate product, and Novartis and Lilly market competitive ADHD products. If 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 received marketing approval for Vyvanse, an amphetamine pro drug for the treatment of ADHD which, although a stimulant, may receive favorable scheduling from the DEA, which could give that product a competitive advantage in the ADHD market. In addition, Shire is likely to dedicate substantial resources to the promotion of Vyvanse, which is expected to reduce the level of promotion devoted to Daytrana. These competitive products, especially Vyvanse and those already marketed

**Table of Contents**

by Shire, may negatively impact Shire's ability to gain market share for Daytran 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 have a significant disadvantage against 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 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 countries in other regions 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

**Table of Contents**

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.

**Our quarterly operating results are subject to significant fluctuations.**

In 2006, 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, 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 spending resulting from the timing of clinical trials. In addition, Novartis is entitled to an annual \$6.1 million preferred return over our interest in Novogyne, 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



**Table of Contents**

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.

**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. In addition, managed care agreements established by Novartis could 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, as well as

**Table of Contents**

requiring the government to negotiate directly with drug companies for lower prices in the Medicare prescription drug plan. 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 six cases in which a plaintiff alleges personal injury from the use of HT products which we manufacture and Novogyne distributes. In addition, Novartis has advised us that Novartis has been named as a defendant in at least 31 additional lawsuits involving approximately 33 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<sup>®</sup>, Vivelle<sup>®</sup> and CombiPatch<sup>®</sup>. Novogyne has been named as a defendant in one lawsuit in addition to the lawsuits referenced above. If any such claims against us are successful, we may be required to make significant 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 and Novogyne maintain product liability insurance, but there can be no assurance that such insurance will cover all future claims or that we and/or Novogyne will be able to maintain existing coverage or obtain additional coverage at reasonable rates. Over the past few years, the cost of 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 coverage is insufficient, we and/or Novogyne may incur significant liability payments that would negatively affect our business, financial position and results of operations. Novogyne has a claims-made insurance policy with a \$10.0 million aggregate limit, and as of December 31, 2006, Novogyne has recorded an insurance receivable of \$7.3 million.

**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. The amount of our coverage may not be sufficient to cover the full amount of a covered loss. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse

**Table of Contents**

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.

**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, especially for property, business interruption and products liability coverage. These and other types of coverage also have become less widely available and more difficult to obtain. In response, we increased deductibles and decreased certain coverages to mitigate these costs while still paying higher premiums. 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 us, 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

**Table of Contents**

predict in advance what amounts we might be obligated to pay Novogyne or Novartis under these indemnification provisions or, alternatively, what obligations may be owed to us by these parties, including as they relate to potential damages, settlement amounts and defense costs associated with the product liability lawsuits that relate to 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 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

**Table of Contents**

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 2006, our common stock traded as low as \$14.50 per share and as high as \$26.22 per share. Any number of factors, including some over which we have no control and some unrelated to our business or financial results, may have a significant impact on the market price of our common stock, including: announcements by us or our competitors of technological innovations or new commercial products, changes in governmental regulation, receipt by us or one of our competitors of regulatory approvals or adverse regulatory determinations, developments relating to our patents or proprietary rights of one of our competitors, publicity regarding actual or potential medical results or risks for products that we or one of our competitors market or has under development, and period-to-period changes in financial results and the economy generally. We, like any other company with a volatile stock price, may be subject to further securities litigation, which could have a material adverse effect on our business and financial results.

**Item 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 1992 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 (\$0.7 million at December 31, 2006). 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 17,600 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.

**Table of Contents**

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 entered an order 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.

In April 2006, an individual plaintiff and her husband filed a complaint in the United States District Court, District of Minnesota against Noven, Novogyne, Novartis, Wyeth Inc. and Wyeth Pharmaceuticals, Inc. alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including our CombiPatch® product. The plaintiffs claim compensatory and other damages in an unspecified amount.

In July 2006, four complaints were filed in the United States District Court, District of Minnesota against Noven and other pharmaceutical companies by four separate individual plaintiffs, each filing alone or with her husband. Three of the complaints also name Novartis as a defendant, and of these, two name Novogyne as a defendant as well. Each complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle® in one case and CombiPatch® in two of the cases. The plaintiffs in each case claim compensatory and other damages in an unspecified amount.

We intend to defend all of the foregoing lawsuits vigorously, but the outcome of these product liability lawsuits cannot ultimately be predicted.

Novartis has advised us that Novartis has been named as a defendant in at least 31 lawsuits that include approximately 33 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 four lawsuits 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.

**Table of Contents**

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, 2006.

**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, 2007. 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., Ph.D. Dr. Abrao, age 64, 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 46, 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 41, 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 54, has been with Noven since February 1997 and, since November 2000, has served as Vice President Marketing & Sales. From 1981 through 1997, he served Ciba-Geigy Corporation in a variety of sales and marketing positions, most recently as Executive Director of Marketing.

Juan A. Mantelle Mr. Mantelle, age 48, 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

**Table of Contents**

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 65, 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.



**Table of Contents****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, 2007, we had 254 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, 2006	\$26.22	\$21.25
Third Quarter, 2006	25.48	17.69
Second Quarter, 2006	19.10	16.30
First Quarter, 2006	18.17	14.50
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

The following table provides information with respect to our stock repurchases during the fourth quarter of 2006:

	Total Number of Shares Purchased as Part of	Average Price Paid Per Share	Total Number of Shares Purchased Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program <sup>1</sup>
October 1, 2006 to October 31, 2006				\$23,711,040
November 1, 2006 to November 30, 2006				\$23,711,040
December 1, 2006 to December 31, 2006				\$23,711,040
Totals				\$23,711,040

<sup>1</sup> 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**

**Comparison of Five-Year Cumulative Total Return\***

Noven Pharmaceuticals, Inc., Russell 2000 Index and Value Line Drugs Index  
(Performance Results Through 12/31/06)

	2001	2002	2003	2004	2005	2006
Noven Pharmaceuticals	\$ 100.00	\$52.00	\$ 85.69	\$ 96.11	\$ 85.24	\$143.38
Russell 2000 Index	\$100.00	\$78.42	\$114.00	\$133.38	\$137.81	\$161.24
Value Line Drugs Index	\$100.00	\$82.59	\$105.97	\$105.02	\$115.49	\$133.02

\* Cumulative total return assumes reinvestment of dividends.

**Source: Value Line, Inc.**

**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,				
	2006 <sup>1</sup>	2005 <sup>2</sup>	2004	2003	2002
Statement of Operations Data:					
Net Revenues:					
Product revenue	\$ 48,326	\$ 40,451	\$ 36,871	\$ 37,116	\$ 50,199
Contract and license revenue	12,363	12,081	9,020	6,050	5,173
Total net revenues	60,689	52,532	45,891	43,166	55,372
Expenses:					
Cost of products sold	36,508	34,047	20,514	19,845	23,297
Research and development	11,454	13,215	9,498	7,719	11,310
Marketing, general and administrative	21,701	16,915	17,271	15,858	14,257
Total expenses	69,663	64,177	47,283	43,422	48,864
(Loss) income from operations	(8,974)	(11,645)	(1,392)	(256)	6,508
Equity in earnings of Novogyne	28,632	24,655	17,641	17,094	14,368
Interest income, net	4,272	2,242	999	659	822
Income before income taxes	23,930	15,252	17,248	17,497	21,698
Income tax expense	7,942	5,280	6,024	6,301	7,819
Net income	\$ 15,988	\$ 9,972	\$ 11,224	\$ 11,196	\$ 13,879
Basic earnings per share	\$ 0.67	\$ 0.42	\$ 0.48	\$ 0.50	\$ 0.62
Diluted earnings per share	\$ 0.66	\$ 0.42	\$ 0.46	\$ 0.49	\$ 0.60
Balance Sheet Data:					
Cash and cash equivalents	\$ 9,144	\$ 66,964	\$ 93,958	\$ 83,381	\$ 58,684

Short-term investments	144,455	17,900			
Total assets	281,365	185,910	201,975	170,984	138,502
Capital lease obligation	388	121	235		5
Deferred license revenue	89,272	23,655	39,085	50,005	29,445
Stockholders' equity	176,675	140,621	129,039	108,823	96,741

<sup>1</sup> Our results for 2006 included \$3.3 million in stock-based compensation expenses resulting from the adoption of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment .

<sup>2</sup> Our results for 2005 included \$9.9 million in charges associated with the write-off of fentanyl inventories and associated destruction charges, and the recognition of \$5.7 million in fentanyl deferred license revenues, resulting from the FDA's decision not to approve our application for a generic fentanyl patch.

**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 2006 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 2007;

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 2006 financial statements and the related notes thereto included in this Form 10-K.

**Executive Summary**

*The following 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 in our financial statements and related notes included in this Form 10-K.*

For Noven, the highlights of the year ended December 31, 2006 included the approval and launch of Daytrana, the first transdermal therapy for ADHD and our first product commercialized outside the HT category, as well as record financial results reported by our Novogyne joint venture.

Daytrana was approved by the FDA in April 2006, triggering a \$50 million approval milestone payment from Shire. Our results for 2006 included the recognition of \$5.9 million in license revenues associated with Daytrana milestones, as well as \$8.6 million in Daytrana product sales to Shire. Primarily due to Daytrana product and license revenues, our 2006 net revenues increased to \$60.7 million, a 16% increase over 2005. In 2005, our net revenues benefited from the recognition of \$6.0 million in deferred license revenues in connection with our collaboration with Endo, of which \$5.7 million (the Fentanyl Revenues) was associated with the FDA's decision to cease review of our application for a generic fentanyl patch. Those same circumstances caused us to record in 2005 an aggregate \$9.9 million in charges associated with the write-off and destruction of our fentanyl inventories (the Fentanyl Charges).

Our gross margin percentage for 2006 was 24%, substantially lower than what our gross margin in 2005 would have been but for the Fentanyl Charges. Our 2006 gross margin was adversely affected by, among other things, startup costs and related inefficiencies associated with the scale-up and expedited production of Daytrana launch quantities in the 2006 second quarter, as well as increased overhead costs associated with facility expansion for new products and quality-related improvements. Due in part to our continuing efforts to improve efficiencies and reduce costs, including a 2006 third quarter cost reduction program, we reported improvements in gross margin percentage in the second half of the year. Specifically, our overall gross margin percentage increased from 11% in the second quarter to 30% in each of the third and fourth quarters of 2006.

**Table of Contents**

Research and development expenses for 2006 decreased \$1.8 million, or 13%, to \$11.5 million, primarily due to reduced development expenses related to our developmental fentanyl patch and Daytrana. Marketing, general and administrative expenses increased \$4.8 million, or 28%, to \$21.7 million, primarily as a result of the recognition of \$2.5 million in stock-based compensation expenses due to the adoption of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ) in 2006, a \$1.1 million increase in personnel costs and a \$0.6 million termination charge related to the 2006 third quarter cost reduction program.

We recognized \$28.6 million in earnings from Novogyne in 2006, an increase of 16% compared to 2005. Interest income for 2006 increased \$2.0 million, or 91%, over 2005, largely reflecting a higher average cash balance in 2006 resulting from the receipt of a \$50.0 million approval milestone payment from Shire. For 2006, we reported net income of \$16.0 million (\$0.66 diluted earnings per share), compared to net income of \$10.0 million (\$0.42 diluted earnings per share) reported in 2005. Net income in 2005 reflected the impact of both the Fentanyl Revenues and the Fentanyl Charges.

Our Novogyne joint venture reported net revenues of \$131.9 million, a 9% increase over 2005, reflecting increased sales of Vivelle-Dot® (the market leading product in the transdermal estrogen therapy category) partially offset by increased sales and returns allowances. Novogyne's selling, general and administrative expenses for 2006 increased 5% to \$37.3 million, primarily reflecting increased marketing, sample and promotional spending in support of Vivelle-Dot®. Novogyne's 2006 net income increased 13% to \$65.3 million compared to 2005.

At December 31, 2006, Noven had an aggregate \$153.6 million in cash and cash equivalents and short-term investments, compared to \$84.9 million at December 31, 2005. In February 2007, Shire notified us that its net sales of Daytrana in 2006 were sufficient to trigger payment of the first of three potential \$25.0 million milestones to Noven. We received that payment in the first quarter of 2007. For accounting purposes, we expect to defer the revenue associated with the Daytrana sales milestones and recognize them as license revenues on a straight line basis through the first quarter of 2013.

Prescription demand for our two lead products increased during 2006. Total prescriptions for Vivelle-Dot® increased 6% in 2006 compared to 2005, and total prescriptions for Novogyne's products, taken as a whole, increased 3% for the same period. Total prescriptions for Daytrana increased 69% in the fourth quarter of 2006 compared to the third quarter of 2006, which was the first complete quarter following the product's launch. The increase in Daytrana prescriptions reflects initial uptake of a newly-launched product and is not indicative of the product's ongoing growth rate.

**Overview of Noven and our Novogyne Joint Venture**

We develop and manufacture advanced transdermal patches, offering commercial products in both the ADHD and HT categories. We presently derive a significant portion of our revenues, and an even greater percentage of our profits, from sales of HT patches. In the United States, our HT products are marketed and sold by Novogyne Pharmaceuticals, our joint venture with Novartis. 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

**Table of Contents**

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 our HT 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. Novartis is entitled to an annual \$6.1 million preferred return over our interest in 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 \$28.6 million, \$24.7 million and \$17.6 million in 2006, 2005 and 2004, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne with respect to our equity in its earnings is in the form of cash distributions declared by Novogyne's Management Committee. Accordingly, the amount of cash distributions 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 2006, 2005 and 2004, we received \$26.4 million, \$26.2 million and \$18.1 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.

The market for HT products, including transdermals, significantly declined in the years following the July 2002 publication of the WHI study that found adverse health risks associated with HT, and in current periods the market continues to decline. Comparing the fourth quarter of 2005 to the fourth quarter of 2006, total prescriptions dispensed in the HT market in the United States decreased 3%. Comparing the same periods, aggregate prescriptions for our United States HT products increased 3%. Total prescriptions in the estrogen segment of the HT market in the United States decreased 4% comparing the same periods, while prescriptions for our Vivelle® line of products increased 4%. Vivelle-Dot®, which represented 87% of our total United States HT prescriptions in the fourth quarter of 2006, increased 5% from the fourth quarter of 2005. We believe that Vivelle-Dot® patch prescriptions have benefited from patient conversions from the original Vivelle® product (the predecessor product to Vivelle-Dot®), which represented 3% of our total United States prescriptions in the fourth quarter of 2006. Vivelle® is in the process of being discontinued in several jurisdictions where our advanced Vivelle-Dot® ET patch has gained acceptance. We ceased manufacturing of Vivelle® for the United States market at the end of 2006.

United States prescriptions for our CombiPatch® product (which represented approximately 10% of our total United States HT prescriptions in the fourth quarter of 2006) decreased 11% from the fourth quarter of 2005 to the fourth quarter of 2006, while prescriptions for the total United States market for fixed combination hormone therapy decreased 5%. The combination therapy arm of the WHI studies involved an oral combination estrogen/progestin product and, accordingly, the combination therapy segment of the HT market has experienced the most significant decline. Further decreases above expectations for our CombiPatch® product (whether as a result of the WHI studies, competition in the category 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.



**Table of Contents**

**Certain Items that May Affect Historical or Future Comparability**

*Daytrana*

The DEA controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing. In 2006, we received an initial grant of methylphenidate quota from the DEA. We submitted supplemental applications for additional quota to fulfill 2006 product orders received from Shire. The DEA granted additional 2006 quota in November 2006, but less than we had requested, and later than required to fulfill 2006 product orders. As a result, we ended the year with \$8.6 million in full-year Daytrana sales to Shire and approximately \$1.0 million in Daytrana product backorders that we fulfilled in the first quarter of 2007.

The reduction in Daytrana revenues negatively affected our gross margin in the fourth quarter of 2006. Our ability to produce Daytrana and improve the gross margins from the sale of this product is contingent on, among other things, receiving a sufficient supply of the active methylphenidate ingredient from Shire as well as sufficient quota from the DEA for this controlled substance. At any given time, we expect to have applications pending with the DEA for annual or additional procurement quota that may be critical to continued production. Any delay or stoppage in the supply of the active methylphenidate ingredient could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations.

We have received reports concerning difficulty removing the release liner from a small percentage of Daytrana patches. Although the product meets specifications, during the first quarter of 2007, we implemented enhancements intended to make Daytrana easier to use. If Daytrana sales are materially impacted because of this issue, then Noven's results of operations and financial condition would likely be adversely affected.

*Stock-based Compensation Expense*

Currently, our outstanding stock-based compensation consists of: (i) stock options; (ii) stock-settled appreciation rights (SSARs); and (iii) for our non-employee directors, restricted stock awards. Prior to January 1, 2006, all awards granted to employees under the 1999 Long-Term Incentive Plan (the 1999 Plan) were stock options. In 2006, we began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options, and from time to time we may consider or grant other forms of stock-based compensation.

Prior to 2006, stock-based compensation expense was not required to be recognized in our statements of operations. On January 1, 2006, we adopted the provisions of, and accounted for stock-based compensation in accordance with, SFAS 123(R), which requires us to expense the fair value of stock-based compensation awards in our statement of operations. We elected the modified-prospective method, under which prior periods are not revised for comparative purposes. Total pre-tax stock-based compensation expense recognized in our statements of operations for 2006 was \$3.3 million, of which \$2.5 million was recognized in marketing, general and administrative and \$0.4 million was recognized in each of research and development and cost of products sold, respectively. There were no stock-based compensation costs capitalized as part of inventory or fixed assets for 2006.

**Table of Contents**

At December 31, 2006, the unamortized compensation expense that we expect to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock, as determined in accordance with SFAS 123(R), is approximately \$8.3 million before the effect of income taxes, of which \$3.5 million, \$2.4 million, \$1.6 million and \$0.8 million is expected to be incurred in 2007, 2008, 2009 and 2010, 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.

In order to eliminate some of the future compensation expense that we would otherwise have recognized in our statements of operations under SFAS 123(R), during 2005, we accelerated the vesting of certain stock options under the 1999 Plan. As a result of this action, options to purchase approximately 1.1 million shares of our common stock became immediately exercisable, including options held by our executive officers to purchase approximately 455,000 shares. As a result of the acceleration, during 2005, we eliminated approximately \$10.1 million of compensation expense, net of applicable income taxes, from our future statements of operations, however, this expense is included in the pro forma footnote disclosure for the year ended December 31, 2005.

**Results of Operations****Revenues:**

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

	2006	% Change	2005	% Change	2004
Product revenues Novogyne:					
Product sales	\$ 19,714	(1%)	\$ 19,910	6%	\$ 18,798
Royalties	6,845	6%	6,444	24%	5,204
	26,559	1%	26,354	10%	24,002
Product revenues third parties:					
Product sales	21,422	55%	13,779	12%	12,327
Royalties	345	8%	318	(41%)	542
	21,767	54%	14,097	10%	12,869
Total product revenues	48,326	19%	40,451	10%	36,871
Contract and license revenues:					
Contract	1,966	(22%)	2,528	(50%)	5,021
License	10,397	9%	9,553	139%	3,999
	12,363	2%	12,081	34%	9,020
Net revenues	\$ 60,689	16%	\$ 52,532	14%	\$ 45,891

**Net Revenues**

As described in more detail below, the 16% increase in 2006 net revenues as compared to 2005 was primarily attributable to the launch of Daytrana, which contributed \$8.6 million to our product revenues and \$5.9 million to our license revenues in 2006.

The 14% increase in 2005 net revenues as compared to 2004 was attributable to an increase in license revenues related to the recognition of \$6.0 million of license revenue from our fentanyl agreement with Endo which is described in more detail below. In addition, there was an aggregate



**Table of Contents**

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.

**Product Revenues – Novogyne**

Product revenues – Novogyne consists of our sales of Vivelle-Dot®, Vivelle®, Estradot® for Canada and CombiPatch® to Novogyne at a fixed price for product sampling and 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.

Revenues from Novogyne in 2006 were relatively consistent with 2005. The \$2.4 million increase in revenues from Novogyne for 2005 as compared to 2004 was 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 and price increases at Novogyne. The decline in unit sales of Estradot® was primarily attributable to fulfilling orders in 2004 related to a planned transition from Vivelle® to Estradot® in Canada. Price was not a contributing factor to the overall increase.

**Product Revenues – Third Parties**

Product revenues – third parties consists 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. Product revenues – third parties also includes sales of Femiest to Aventis for resale in Japan. Beginning in the second quarter of 2006, product revenues – third parties also includes sales of Daytrana® to Shire for resale in the United States.

The \$7.7 million increase in product revenues from third parties for 2006 as compared to 2005 was primarily related to \$8.6 million in unit sales of Daytrana, reflecting initial product launch. This increase was partially offset by a \$0.9 million decline in the recognition of the price reconciliation payments received from Novartis Pharma. Noven records such 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 sold the product to Novartis Pharma. Volume increases of \$0.9 million and \$0.2 million for Estradot® and Femiest, respectively, were offset by volume declines of \$0.7 million and \$0.4 million for Estalis® and Menorest, respectively. We believe the volume increases and declines were all related to the timing of orders, except for the decline in Menorest, which was attributable to the continued transition from Menorest to Estradot®.

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

**Table of Contents**

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.

**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 development work and success milestone payments. License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements.

Contract revenues declined \$0.6 million for 2006 as compared to 2005 due to a decline in contract work performed. License revenue increased \$0.8 million for 2006 as compared to 2005 primarily due to the recognition of \$5.9 million in Daytrana license revenues and the recognition of a \$1.0 million one-time non-refundable payment from a third party for a license to certain of our patents, partially offset by \$6.0 million in license revenue recognized in 2005 related to our fentanyl agreement with Endo that did not recur in 2006. Included in the \$6.0 million of license revenue in 2005 was \$5.7 million that was recognized in the fourth quarter of 2005 due to the termination of our fentanyl agreement with Endo upon the FDA's decision to cease review of our fentanyl patch application.

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 primarily attributable to the recognition of the remaining deferred revenue balance related to our fentanyl agreement with Endo as discussed above.

**Gross Margin:**

This section discusses our gross margin percentages relating to our product revenues (i) across all of our products ( Overall Gross Margin ), (ii) on our product revenues from Novogyne ( Gross Margin Novogyne ), which for accounting purposes is considered a related party, and (iii) on our product revenues from third parties ( Gross Margin Third Parties ). Product revenues from third parties primarily include HT product sales to Novartis Pharma for resale primarily outside the U.S. and Japan, as well as Daytrana product sales to Shire.

This section includes a non-GAAP analysis of gross margins that excludes an aggregate \$9.9 million charge to cost of products sold in 2005 relating to the write-off and destruction of fentanyl pre-launch inventories (the Fentanyl Charge ). We took this charge following the FDA's decision in September 2005 to cease review of our fentanyl patch ANDA. We believe such a non-GAAP analysis is useful to investors in order to meaningfully evaluate our ongoing, underlying business and compare our 2005 financial results to other years. For the same reasons, management uses this non-GAAP analysis to evaluate Noven's ongoing, underlying business. This analysis should not be considered an alternative to measures computed in accordance with GAAP, nor should it be considered an indicator of our overall financial performance.

The allocation of overhead costs impacts our determination of gross margins for each of our products. Overhead costs, which were in excess of \$20.0 million in 2006, consist of salaries and

**Table of Contents**

benefits, supplies and tools, equipment costs, depreciation, and insurance costs and represent a substantial portion of our inventory production costs. The allocation of overhead among our various products requires us to make significant estimates that involve subjective and often complex judgments. Using different estimates would likely result in materially different results for Gross Margin Novogyne and Gross Margin Third Parties than are presented in the gross margin table below.

Our gross margins are summarized as follows (dollar amounts in thousands):

	2006	2005	2004
<b>Overall Gross Margin:</b>			
Product revenues	\$ 48,326	\$ 40,451	\$ 36,871
Cost of products sold	36,508	34,047	20,514
Gross profit (product revenues less cost of products sold)	11,818	6,404	16,357
Gross margin (gross profit as a percentage of product revenues)	24%	16%	44%
Fentanyl Charge		9,917	
Gross profit excluding Fentanyl Charge	11,818	16,321	16,357
Gross margin excluding Fentanyl Charge	24%	40%	44%
	2006	2005	2004
<b>Gross Margin Novogyne:</b>			
Product revenues	\$ 26,559	\$ 26,354	\$ 24,002
Cost of products sold	14,102	13,547	11,413
Gross profit (product revenues less cost of products sold)	12,457	12,807	12,589
Gross margin (gross profit as a percentage of product revenues)	47%	49%	52%

**Table of Contents**

	2006	2005	2004
<b>Gross Margin Third Parties:</b>			
Product revenues	\$ 21,767	\$ 14,097	\$ 12,869
Cost of products sold	22,406	20,500	9,101
Gross profit (loss) (product revenues less cost of products sold)	(639)	(6,403)	3,768
Gross margin (gross profit (loss) as a percentage of product revenues)	(3%)	(45%)	29%
Fentanyl Charge		9,917	
Gross (loss) profit excluding Fentanyl Charge	(639)	3,514	3,768
Gross (loss) margin excluding Fentanyl Charge	(3%)	25%	29%

In general, our sales of HT products to Novogyne for resale in the U.S. have a higher gross margin than our other products, reflecting favorable pricing, larger production orders and other factors. Our sales of HT products to Novartis Pharma for resale in international markets generally have a lower gross margin than sales of HT products sold to Novogyne due to, among other things, unfavorable pricing environments in foreign markets, and smaller production orders. Our gross margin on product sales of Daytrana to Shire has been negatively affected by, among other things, costs and inefficiencies associated with the commencement of commercial production of the product. As discussed below, we are working to improve the profitability of Daytrana product sales, but we cannot assure that we will be successful.

During the years presented in the gross margin tables, we have expanded our facilities and increased staffing for the production of fentanyl, Daytrana, and other developmental products (the Expansion Activities). We also have increased personnel and other resources dedicated to quality control in our HT product line (HT Quality Improvements). Together, these initiatives expanded and improved our production infrastructure, but they also increased overhead and negatively affected our gross margins. Our ability to improve gross margins from current levels is dependent in part on our ability to launch new commercial products that leverage this infrastructure and assist in the absorption of overhead, as well as on our ability to control and/or reduce costs. We cannot assure that we will be successful in improving our gross margins in future periods.

We implemented a cost reduction program in the third quarter of 2006 to reduce costs and improve efficiencies in our operations (the Cost Reduction Program). We believe this program will result in annual pre-tax savings of up to \$1.8 million, the majority of which will be recognized in manufacturing costs. This program contributed to an improved Overall Gross Margin in the second half of 2006.

We sell Daytrana finished product to Shire at a fixed cost, so our profit on product sales of Daytrana depends on our ability to manufacture the product efficiently. Start-up expenses and

**Table of Contents**

production inefficiencies associated with the commencement of Daytrana production, including lower than desired yields and increased costs associated with meeting launch timelines (together, the Daytrana Launch Costs), negatively affected Overall Gross Margin and Gross Margin – Third Parties in 2006. In addition, the cost of the active methylphenidate ingredient (AMI) used in the production of Daytrana is not included in our Daytrana product revenues or in our cost of products sold. Shire supplies us with AMI for production of Daytrana, and retains title to the AMI. Under this arrangement, we bear certain risks of manufacturing loss related to AMI and are obligated to reimburse Shire for the cost of AMI if our production yields do not meet certain minimum levels. For 2006, our cost of products sold included \$0.4 million in AMI reimbursements to Shire which negatively affected Overall Gross Margin and Gross Margin – Third Parties in 2006. For 2006, Daytrana product revenues were \$8.6 million, and cost of products sold related to Daytrana was \$10.5 million, primarily reflecting the impact of the Daytrana Launch Costs and the AMI reimbursements.

Our Overall Gross Margin was 29%, 11%, 30% and 30% in the first, second, third and fourth quarters of 2006, respectively. The decline in the 2006 second quarter primarily reflects the Daytrana Launch Costs and AMI reimbursements. The improvement in the third and fourth quarters primarily reflects improved efficiencies and yields in Daytrana production, as well as cost savings associated with the third quarter Cost Reduction Program. We cannot assure that we will be able to continue to improve Overall Gross Margin. Our expectations for gross margins in future periods are addressed under Outlook below.

The decline in Overall Gross Margin in 2005 compared to 2004 (excluding the impact of the Fentanyl Charge) was primarily related to costs associated with the Expansion Activities. The decline in Gross Margin – Novogyne in 2005 compared to 2004 reflected costs associated with the HT Quality Improvements. In addition, Gross Margin – Novogyne in 2004 benefited from a \$0.6 million reduction in allowances for returns that had been established in 2003, based upon our review and analysis of historical and expected future returns. The decline in Gross Margin – Third Parties in 2005 compared to 2004 (excluding the impact of the Fentanyl Charge) was primarily related to higher costs associated with the Expansion Activities, partially offset by a \$0.7 million increase in price adjustment payments in 2005.

**Operating Expenses:**

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

	2006	% Change	2005	% Change	2004
Research and development	\$ 11,454	(13%)	\$ 13,215	39%	\$ 9,498
Marketing, general and administrative	21,701	28%	16,915	(2%)	17,271

**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.



**Table of Contents**

The \$1.8 million decrease in 2006 as compared to 2005 was primarily attributable to a \$3.2 million decline in development engineering expenses related to our methylphenidate and fentanyl patches, partially offset by a \$0.4 million increase in stock-based compensation, a \$0.4 million increase in personnel costs and a \$0.3 million increase in other costs associated with the development of other products.

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.

**Marketing, General and Administrative**

The \$4.8 million increase in marketing, general and administrative expenses in 2006 as compared to 2005 was primarily attributable to \$2.5 million in stock-based compensation expenses resulting from the adoption of SFAS 123(R) in 2006, a \$1.1 million increase in compensation expense primarily due to the addition of personnel in business development, strategic alliances and other key areas and a \$0.6 million charge associated with the elimination of employee positions as part of the cost reduction program discussed in our gross margin section above. Consulting costs increased \$0.6 million due to the timing of work performed on projects related to our compliance with the Sarbanes-Oxley Act of 2002 and to a lesser extent increased information management compliance costs.

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 and \$0.5 million related to the reduction of our allowance for costs related to product recalls established in 2004. These reductions were partially offset by a \$0.9 million increase in costs associated with expansion activities for anticipated new product launches.

**Other Income and Expenses:**

**Interest Income**

Interest income increased \$2.0 million, or 91%, in 2006 as compared to 2005 due to an increase in the average cash balance, which was primarily attributable to the \$50.0 million milestone payment received from Shire in April 2006 in connection with the approval of our Daytrana product as well as \$13.2 million received from the exercise of stock options. In addition to higher average cash balances, we invested a higher portion of our cash in short-term investments which primarily consist of investment grade, asset backed, variable debt obligations and municipal auction rate securities that yielded higher interest income. We also benefited from an increase in interest rates in 2006 as compared to 2005.

Interest income increased \$1.2 million, or 124%, in 2005 as compared to 2004 and was primarily attributable to the investing of a portion of our cash into short-term investments, as described above, that yielded higher interest income as well as an increase in interest rates.

**Income Taxes**

Our effective tax rate was 33% for 2006, and 35% for 2005 and 2004, respectively. The decrease in our effective tax rate for 2006 as compared to the prior year relates primarily to higher

**Table of Contents**

non-taxable interest income as a percentage of taxable income. This decreased tax rate was partially offset by higher taxable income in 2006 as compared to 2005 primarily due to the Fentanyl Charge in the prior year, non-deductible stock-based compensation expense related to incentive stock options that began in 2006 and certain credits and reductions for reserves for Internal Revenue Service audits that occurred in the prior period that did not recur in the current period. The provision for income taxes is based on the Federal statutory and state income tax rates.

Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the asset is expected to be 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, 2006, we had a net deferred tax asset of \$12.7 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 2006, 2005 and 2004 for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne's earnings as Equity in earnings of Novogyne on our Statements of Operations.

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

	2006	% Change	2005	% Change	2004
Gross revenues <sup>1</sup>	\$ 154,901	13%	\$ 136,901	10%	\$ 124,791
Sales allowances	17,226	20%	14,408	10%	13,154
Sales returns allowances	5,732	N/M	936	N/M	6,224
Sales and returns allowances	22,958	50%	15,344	(21%)	19,378
Net revenues	131,943	9%	121,557	15%	105,413
Cost of sales	30,149	5%	28,696	3%	27,755
Gross profit	101,794	10%	92,861	20%	77,658
Gross margin percentage	77%		76%		74%
Selling, general and administrative expenses	37,318	5%	35,568	(0%)	35,624
Income from operations	64,476	13%	57,293	36%	42,034
Interest income	841	82%	461	141%	191
Net income	\$ 65,317	13%	\$ 57,754	37%	\$ 42,225
Noven's equity in earnings of Novogyne	\$ 28,632	16%	\$ 24,655	40%	\$ 17,641

N/M Not Meaningful



**Table of Contents**

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.

**Novogyne Revenues**

Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies. As has historically been the case, the timing of purchases by trade customers is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying prescription trends in any given period or coincide with Novogyne's quarterly financial reporting periods. As a result, the timing of orders by trade customers is difficult to predict and can lead to significant variability in Novogyne's results, especially when comparing quarterly periods.

Novogyne's gross revenues increased \$18.0 million for 2006 as compared to 2005. By product, the increase in Novogyne's gross revenues reflects a \$19.2 million increase in sales of Vivelle-Dot®/Estradot®, partially offset by a \$0.9 million and a \$0.3 million decline in sales of Vivelle® and CombiPatch®, respectively. The higher Vivelle-Dot®/Estradot® sales were primarily attributable to a \$11.2 million increase in unit sales due to an increase in prescriptions as well as the timing of orders, and an \$8.0 million increase related to pricing. The decline in Vivelle®, our first generation estrogen patch, is due to a \$1.2 million decline in unit sales due to product maturity and the planned discontinuation of the product, partially offset by a \$0.3 million increase related to pricing. The decline in CombiPatch® was due to a \$1.2 million decline in unit sales as a result of the continuing decline in the market for combination therapies as well as the impact of a competitive product. This CombiPatch® decline was partially offset by a \$0.9 million increase related to pricing.

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 pricing. 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**

The following table describes Novogyne's sales and returns allowances for the years ended December 31, 2006, 2005 and 2004 (dollar amounts in thousands):

	2006	% of gross revenues	2005	% of gross revenues	2004	% of gross revenues
Gross revenues	\$ 154,901		\$ 136,901		\$ 124,791	
Managed health care rebates	10,117	7%	8,018	6%	7,898	6%
Cash discounts	3,042	2%	2,690	2%	2,425	2%
Medicaid, Medicare & State program rebates and credits including prescription drug saving cards	981	1%	938	1%	1,341	1%
Chargebacks, including hospital chargebacks	1,032	1%	970	1%	861	1%
Other discounts	2,054	1%	1,792	1%	629	1%
Sales allowances	17,226	11%	14,408	11%	13,154	11%
Sales returns allowances	5,732	4%	936	1%	6,224	5%
Sales and returns allowances	22,958	15%	15,344	11%	19,378	16%
Net revenues	\$ 131,943		\$ 121,557		\$ 105,413	

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 years ended December 31, 2006, 2005 and 2004 was as follows (amounts in thousands):

	2006	2005	2004
Current year provisions for returns of expiring product	\$ 4,342	\$ 3,384	\$ 8,342
Adjustment to prior year provisions for returns of expiring product	1,390	(2,385)	1,227
Benefits for returns for product recalls		(63)	(3,345)
Sales returns allowances	\$ 5,732	\$ 936	\$ 6,224
Actual returns for expiring product	(3,962)	(3,897)	(8,675)
Actual returns for product recalls		(40)	(2,620)

Total actual returns	\$ (3,962)	\$ (3,937)	\$ (11,295)
----------------------	------------	------------	-------------

The increase in sales returns allowances as a percentage of gross revenues for 2006 as compared to 2005 was primarily due to higher than expected returns of Vivelle-Dot® as well as higher than expected returns of CombiPatch®, which resulted in an increase of prior year provisions for returns of \$1.4 million. In addition, 2005 benefited from a reduction in allowances of expiring product due to lower than expected returns as a result of a decline in actual returns of Vivelle® at the time.

**Table of Contents**

The decrease in sales returns allowances as a percentage of gross revenues 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. As a result of this analysis, allowances related to prior years were reduced by \$2.4 million.

**Novogyne Gross Margin**

Novogyne's gross margin was consistent for 2006 as compared to 2005. 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.

**Novogyne Selling, General and Administrative**

Novogyne's selling, general and administrative expenses increased \$1.7 million for 2006 as compared to 2005, primarily due to a \$1.2 million increase in marketing, advertising and promotion expenses and a \$0.7 million increase in sample expenses primarily attributable to the timing of sample orders by Novogyne.

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

**Liquidity and Capital Resources:**

As of December 31, 2006 and December 31, 2005, Noven had the following (amounts in thousands):

	December 31, 2006	December 31, 2005
Cash and cash equivalents	\$ 9,144	\$ 66,964
Short-term investments	144,455	17,900
Working capital	180,821	91,122



**Table of Contents**

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

	2006	2005	2004
Cash flows:			
Operating activities	\$ 60,027	\$ 3,885	\$ 11,869
Investing activities	(133,511)	(32,055)	(7,115)
Financing activities	15,664	1,176	5,823

**Operating Activities:**

Net cash provided by operating activities in 2006 primarily resulted from our receipt of \$50.0 million from Shire related to the final marketing approval of Daytrana by the FDA and \$26.4 million in cash distributions from Novogyne. These receipts were offset by changes in working capital due to the timing of certain payments, including reimbursement payments of \$5.1 million to Shire for clinical trial costs incurred in connection with obtaining Daytrana regulatory approval, \$3.9 million for compensation and related liabilities and \$2.6 million related to insurance.

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 for clinical trial costs incurred in connection with obtaining Daytrana regulatory approval, \$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 \$5.4 million in income taxes, \$2.7 million for purchases of fentanyl, \$2.9 million in clinical trial costs incurred in connection with obtaining Daytrana regulatory approval, \$2.9 million for compensation and related liabilities and \$2.5 million related to insurance.

**Investing Activities:**

Net cash used in investing activities in 2006 was primarily attributable to \$126.4 million in net purchases of short-term investments, as well as the purchase of \$6.3 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 SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities .

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.

**Table of Contents**

Net cash used in investing activities in 2004 was primarily attributable to the purchase of \$6.5 million in fixed assets to expand production capacity for future products.

**Financing Activities:**

Net cash provided by financing activities in 2006, 2005 and 2004 was attributable to \$13.2 million, \$1.3 million and \$5.9 million, respectively, received as the exercise price paid by the option holders in connection with their exercise of stock options. In addition, 2006 benefited from \$2.6 million in excess tax deductions from the exercise of stock options, which prior to the adoption of SFAS 123(R) was reported in operating activities.

**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, 2006, a substantial portion 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 operating cash flow or our short-term liquidity. Although we expect to continue 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 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 and short-term investments or on borrowings to support our operations and business.

In April 2006, Noven received a \$50.0 million milestone payment from Shire as a result of the final marketing approval of Daytrana by the FDA. Shire's net sales of Daytrana exceeded the threshold for the first sales milestone in the fourth quarter of 2006 and, accordingly, we received a \$25.0 million payment from Shire in the first quarter of 2007. Noven may also earn up to two additional \$25.0 million milestone payments upon Shire's achievement of \$50.0 million and \$75.0 million in annual net sales of Daytrana, respectively. Shire commercially launched the product in June 2006. The majority of the income taxes related to the \$50.0 million milestone are expected to be paid in 2007 or early 2008 and the majority of the income taxes related to the first \$25.0 million milestone are expected to be paid in 2008 or early 2009.

Our liquidity in 2006 benefited from \$13.2 million received as the exercise price paid by option holders in connection with their exercise of employee stock options. This number can be expected to fluctuate from year to year depending on the performance of Noven's stock and equity award exercises.

Capital expenditures were \$6.3 million in 2006 and we expect our capital expenditures for full-year 2007 to be approximately in line with 2006 levels. We expect to fund anticipated capital expenditures from our existing cash balances. As a general matter, we believe that we have

**Table of Contents**

sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements.

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

From time to time we may explore the acquisition of one or more technologies, products or businesses that we believe may be complementary to our existing business. We expect to draw upon our cash and short-term investments to fund all or a portion of such potential strategic acquisitions. We may also consider issuing equity securities to fund potential acquisitions. To the extent our existing cash and short-term investments are insufficient to fund any large-scale acquisitions we may be required to seek debt financing or to issue equity or debt securities. If a material acquisition is completed, our results of operations and financial condition could change materially in future periods. If we finance all or any portion of an acquisition through debt financing or debt securities we would be required to devote funds to service and ultimately repay such debt and could be subject to financial or operational covenants that could limit or hinder our ability to conduct our business.

In addition, although we have not repurchased any of our common stock since 2003, it is possible that a portion of our cash and short-term investments could be used to repurchase Noven common stock under our previously-announced stock repurchase program. Stock repurchases, if any, may be made in the open market, including pursuant to a trading program under Rule 10b5-1 promulgated under the Securities Exchange Act of 1934.

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.

**Table of Contents****Aggregate Contractual Obligations**

The table below lists our significant contractual obligations as of December 31, 2006 (amounts are in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations <sup>1</sup>	\$ 7,765	\$ 1,050	\$ 2,019	\$ 1,845	\$ 2,851
Capital Lease Obligation <sup>2</sup>	458	142	283	16	17
Deferred Compensation Obligation	178		136		42
Purchase Obligations <sup>3</sup>	10,785	10,647	138		
Total	\$ 19,186	\$ 11,839	\$ 2,576	\$ 1,861	\$ 2,910

<sup>1</sup> In the ordinary course of business, we enter into operating leases for machinery, equipment, warehouse and office space. Total rental expense for operating leases was \$1.2 million, \$1.1 million and \$0.5 million for the years ended December 31, 2006, 2005 and 2004, respectively.

<sup>2</sup> During 2006 and 2004, Noven entered into capital lease obligations totaling \$0.4 million and \$0.3 million for new equipment, respectively, of which \$0.5 million (including interest) remains outstanding as of December 31, 2006.

<sup>3</sup> 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.

**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 2007 there will not be any material:

acquisitions of products, companies, or technologies or other transactions;

changes in Noven's or Novogyne's accounting or accounting principles or any of the estimates or judgments underlying our critical accounting policies;

regulatory or technological developments;

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

negative actions with respect to our applications for methylphenidate quota or other disruptions in supplies of raw materials;

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,

**Table of Contents**

uncertainties and cautionary factors discussed above under **Risk Factors** beginning on page 21 of this report.

*Daytrana.* As discussed above, during 2006 we received a \$50.0 million milestone payment from Shire relating to the final marketing approval of Daytrana by the FDA. In the fourth quarter of 2006, the first of three potential \$25.0 million Daytrana sales milestones was triggered, resulting in the payment of \$25.0 million from Shire to us in the first quarter of 2007. We expect the second \$25.0 million milestone payment to trigger in 2007, and it is possible that the third milestone will trigger in the same year, in each case depending on the level of Shire's commercial sales of the product. We expect to defer and recognize the approval milestone and all sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is our current best estimate of the end of the useful economic life of the product for accounting purposes. We expect our Daytrana product sales to Shire for full-year 2007 to be between \$16.0 million and \$20.0 million, subject to, among other things, demand for the product and the availability and timing of DEA quota.

*HT Product Revenues.* Given customer orders, prescription trends and other factors, we expect Noven's HT product revenues for full-year 2007 to approximate 2006 levels, with growth in our U.S. HT product revenues expected to offset a decline in our international HT revenues.

*Contract and License Revenues.* We expect contract revenues in 2007 to approximate 2006 levels. We expect license revenues to increase substantially in 2007 compared to 2006, reflecting higher Daytrana license revenues.

*Gross Margin.* Since the launch of Daytrana in the second quarter of 2006, we have worked to reduce costs and improve yields, and we reported significant improvement in our overall gross margin for the third and fourth quarters of 2006 compared to our overall gross margin in the second quarter of 2006. For full-year 2007, we are targeting an overall gross margin in the mid-30% range, subject to a variety of factors, some of which are not within our control. These factors include the availability and timing of methylphenidate quota and our ability to effectively coordinate production between Daytrana and our HT products to improve facility utilization, and our ability to improve yields, and these same factors could cause our overall gross margin in any particular quarter to vary significantly from other quarters in 2007.

*Research and Development Expense.* We expect our research and development expense in 2007 to approach \$16.0 million, depending on our ability to advance certain development projects into human clinical studies during 2007.

*Marketing, General and Administrative Expense.* We expect our marketing, general and administrative expense in 2007 to increase in the 5% range over 2006 levels.

*Stock-Based Compensation Expenses.* Based on the expense associated with stock-based compensation previously awarded, and our estimate of the expense associated with such compensation that may be awarded in the course of 2007, we estimate that our total stock-based compensation expenses for full-year 2007 will be approximately \$4.1 million, compared to \$3.3 million for full-year 2006. All other financial guidance provided in this Outlook includes the effect of our anticipated stock-based compensation expenses.

**Table of Contents**

*Novogyne.* Based on current prescription trends and other factors, we expect Novogyne's full year 2007 net revenues to increase in the 5% range compared to 2006 levels, and we expect Novogyne's net income and profit contribution to Noven for 2007 to increase by close to 10% compared to 2006 levels.

*Tax Matters.* We estimate that our effective tax rate for full-year 2007 will be in the 33% to 35% range, which is consistent with 2006 levels. In 2007 or early 2008, we expect to pay taxes in the \$18.0 million range associated with the \$50.0 million cash milestone payment received from Shire in 2006.

*Capital Expenditures.* We expect our capital expenditures for full-year 2007 to be approximately in line with 2006 levels.

**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 and estimates related to allowance for returns related to product recalls, the fair value of stock-based compensation granted to employees and outside directors, the determination of the net realizable value of the net deferred tax asset and our effective tax rate. 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*

We enter into certain contracts that have various terms and conditions that may have multiple revenue characteristics, including license revenues, contract revenues, product sales, royalties and manufacturing revenues. As prescribed by Emerging Issues Task Force 00-21 Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ), 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. 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

**Table of Contents**

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 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. Management's best estimate of the end of the product life cycle for Daytrana extends through the first quarter of 2013, which results in the annual recognition of approximately \$7.1 million in license revenues for the \$50.0 million approval milestone payment we received from Shire in April 2006. If our estimate of the Daytrana product life cycle should change, we will be required to change the license revenue recognition period on a prospective basis, which may materially change the license revenues that we recognize in any given period. For example, with respect to the \$50.0 million approval milestone payment, we would have recognized \$5.0 million and \$3.8 million in Daytrana license revenues on an annual basis had we determined that the product life cycle ended in the first quarter of 2016 and 2019, respectively.

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 (proportional performance method) 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.

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

**Table of Contents**

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. If our estimate concerning the amount of the product returns is incorrect or if our partners should initiate further unexpected recalls, then our results of operations could be materially different. For example, in 2003, Noven and Novogyne established allowances for the return of recalled product, which had the effect of reducing Noven's and Novogyne's net revenues by \$1.4 million and \$6.5 million, respectively, for the year ended December 31, 2003. Based on a review of available relevant information, including actual product returns and future expected returns, Noven and Novogyne reduced these allowances during the year ended December 31, 2004, which had the effect of increasing net revenues for the year ended December 31, 2004 by \$0.6 million and \$3.3 million for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase Noven's income before income taxes by \$2.2 million for the year ended December 31, 2004.

*Stock-Based Compensation*

On January 1, 2006, we adopted SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. Pre-tax stock-based compensation expense recognized under SFAS 123(R) in 2006 was \$3.3 million.

We currently use the Black-Scholes option pricing model to determine the fair value of stock options and SSARs. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, expected forfeiture rates and expected dividends.

We estimate the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as described in SAB 107. We estimate the volatility of common stock by using a combination of both historical and implied volatility based on an equal weighting of each as management believes that marketplace participants would likely use the expected volatility in determining an exchange price for an option. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense accordingly. If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income, net income and net income per share. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable, characteristics not present in our option grants. Existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our stock-based compensation. Consequently, there is a risk that our estimates of the fair values of our stock-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those stock-based payments in the future. Stock options or SSARs may expire worthless or otherwise result in zero intrinsic value as



**Table of Contents**

compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that are significantly higher than the fair values originally estimated on the grant date and reported in our financial statements. There currently is no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values.

*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 actual FIFO cost of inventory at the end of each reporting period. Historically, standard costs have been substantially consistent with actual costs. In addition, the allocation of overhead costs impacts our estimate of the cost of inventory. Total overhead costs, which were in excess of \$20.0 million in 2006, consist of salaries and benefits, supplies and tools, equipment costs, depreciation and insurance costs and represent a substantial portion of our inventory production costs. The allocation of overhead to inventory production costs and between and among our various products requires us to make significant estimates that involve subjective and often complex judgments, including, among other things, normal production capacity, the relationship between labor costs and overhead costs, the extent of labor that goes into producing products and the amount of overhead costs absorbed in manufacturing inventory. Any change in these assumptions could materially impact our recorded cost of products sold and stated inventory balances.

Our net inventory balances were \$8.7 million and \$7.9 million as of December 31, 2006 and 2005, respectively. We determine the market value of our raw materials, finished product and packaging inventories based upon references to current market prices for such items as of the end of each reporting period and record a write-down of inventory standard cost to market, when applicable. We periodically review our inventory for excess items, and we establish a valuation 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. If our provisions prove to be inadequate, our inventories could be overstated or understated in any given period.

*Pre-Launch Inventories*

Pre-launch inventories consist primarily 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, or any other circumstances that will make our product candidates commercially viable. 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

**Table of Contents**

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.

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. For example, as a result of the FDA's decision to cease its review of our fentanyl patch application in September, 2005, we wrote off the entire fentanyl patch inventory of \$14.0 million, 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. We had capitalized \$10.8 million and \$14.0 million of these inventories as of December 31, 2004 and September 30, 2005, respectively, with the full belief that the FDA would approve the product and it would be launched. Pre-launch inventories of \$2.4 million as of December 31, 2005 consisted of Noven's Daytran product, which received final approval from the FDA in April 2006 and was commercially launched in June 2006. There were no pre-launch inventories at December 31, 2006.

*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, which was \$12.7 million as of December 31, 2006. 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, 2006. 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 and could affect our financial results.

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 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. If we are assessed interest and/or penalties by governing jurisdictions, we include those amounts in our tax provision. We estimated our effective tax rate for 2006 to be 33%, while our effective tax rate for

**Table of Contents**

2005 and 2004 was 35%, respectively. If our effective tax rate was proven to be 35% or higher for 2006, our provision for income taxes would materially vary.

*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.

*Novogyne Intangible Asset*

As of December 31, 2006, Novogyne had a long-term intangible asset of \$26.3 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. In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment of Disposal of Long-Lived Assets* (SFAS 144), the CombiPatch® marketing rights are assessed for impairments whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future net cash flows of the product. This analysis requires Novogyne to make a number of significant assumptions and judgments involving prescription trends, sales price, unit cost and product life cycle among many other factors. In the event the carrying value of the asset exceeds the undiscounted future net cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairments are an inherent risk in the pharmaceutical industry and cannot be predicted. Further declines in CombiPatch® sales (whether as a result of the HT studies, competition in the category or otherwise) could require Novogyne to record an impairment loss related to these marketing rights. As a result of the significance of the CombiPatch® marketing rights, any such impairment loss could have a material adverse impact on Novogyne's and Noven's financial position and/or results of operations.

*Novogyne 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.

**Table of Contents**

The following table describes the activity for the revenue deduction accruals by major category for the year ended December 31, 2006 (amounts in thousands):

	January 1, 2006	Payments	Adjustments of prior years	Income Statement Charge (Reversal) Current Year	December 31, 2006
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	\$ 555	\$ (1,064)	\$ (89)	\$ 1,070	\$ 472
Managed health care rebates	4,135	(9,561)	95	10,022	4,691
Chargebacks, including hospital chargebacks	82	(1,016)		1,032	98
Cash discounts, direct customer discounts & other discounts	817	(5,242)	(2)	5,098	671
Sales returns allowances	6,168	(3,962)	1,390	4,342	7,938
Total	\$ 11,757	\$ (20,845)	\$ 1,394	\$ 21,564	\$ 13,870

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. Novogyne's management believes that due to Novartis' extensive experience, it is able to reasonably estimate these sales deductions.

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 six months after the product is dispensed, any rebate adjustments may involve revisions of accruals for several quarters.

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

**Table of Contents**

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 which funds healthcare benefits to individuals over the age of 65. Individuals that previously had dual Medicaid/Medicare drug benefit eligibility had their Medicaid prescription drug coverage replaced on January 1, 2006, by the new Medicare Part D coverage provided through private prescription drug plans. The change led to a significant shift of plan participants between programs in which products participate. Provisions for Medicare Part D rebates are estimated using a combination of specific terms of individual plan agreements, product and population growth, price increases and the impact of contracting strategies. 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 with remaining shelf lives of six months or less. Novogyne's policy is that no product will be shipped to customers 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 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

**Table of Contents**

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, 2006 and 2005. 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.

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, we can not 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 Loss Contingencies*

Novogyne is required to establish accruals for certain loss contingencies related to litigation, including product liability claims. Novogyne accrues estimated legal fees and settlement costs in accordance with SFAS No. 5,

Accounting for Contingencies. Accruals for product liability claims are recorded by Novogyne, 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. Novogyne includes estimated legal fees in accruals for product liability claims and makes adjustments as new information becomes available. Receivables for insurance recoveries related to product liability claims under Novogyne's third party insurance policy are recorded, on an undiscounted basis, when it is probable that a recovery will be realized. Novogyne's accruals and related receivables for product liability claims and other litigation accruals involve a high level of judgment, including estimates of incurred but not reported claims, estimates of cost per claim for both reported and unreported claims, allocation of cost between Noven, Novartis and Novogyne

**Table of Contents**

based on ownership dates and applicable indemnification and other agreements between them, estimates of insurance recoveries and judgments as to the recoverability of insurance receivables recorded. Since July 2004, Novartis, along with various other pharmaceutical companies, has been named in a number of lawsuits involving Novogyne's hormone replacement therapy products. Novogyne has established reserves in the amount of \$9.6 million as of December 31, 2006 for expected defense and settlement expenses related to pending lawsuits as well as for estimated future cases alleging use of Novogyne's products. In addition, Novogyne has recorded an insurance receivable of \$7.3 million, which is Novogyne's best estimate of the insurance coverage for recovery of claims.

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 from policies in the name of Novogyne. The litigation accruals and estimated insurance recoveries are maintained by Novartis for its business as a whole and those accruals and recoveries relating to Novogyne are estimated by Novartis (based on 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, we can not control Novartis' analysis of the underlying data or its application of that analysis to Novogyne. Litigation and its outcome are inherently difficult to predict. Any change in the estimates of number of cases, cost per case, allocation of cost between Noven, Novartis and Novogyne, insurance recoveries and other assumptions could cause Novogyne's and Noven's financial results to significantly vary. Furthermore, if actual liability and insurance recoveries ultimately differ from that which has been recorded, Novogyne's and Noven's financial results in the period where the liability becomes payable and the insurance is recoverable could be materially affected by the adjustment of the liability and insurance recoveries. No insurance proceeds have been recovered by Novartis on behalf of Novogyne as of December 31, 2006.

**New Accounting Standards**

In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements ( FAS 157 ). This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The adoption of FAS 157 is not expected to have a material impact on our results of operations or financial condition.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ( SAB 108 ), which added Section N to Topic 1, Financial Statements, of the Staff Accounting Bulletin Series effective for fiscal years ending after November 15, 2006. Section N provides guidance on the consideration of the effects of prior year misstatements when quantifying current year financial statement misstatements for the purpose of materiality assessment. The SEC concluded in SAB 108 that a registrant's materiality evaluation of an identified unadjusted error should quantify the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements. If either the carryover or reversing effects of prior year misstatements is material, the misstatements should be corrected in the current year. If correcting an error in the current year for prior year misstatements causes the current year to be materially misstated, the prior year financial statements should be corrected, even though such

**Table of Contents**

revision previously was and continues to be immaterial to the prior year financial statements. SAB 108 was adopted on December 31, 2006 and its adoption did not have a material impact on our results of operations or financial condition.

In July 2006, the FASB issued Interpretation No. 48 Accounting for Uncertainty in Income Taxes ( FIN 48 ) to clarify the accounting for uncertainties related to income taxes that are recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation requires financial statement recognition of the impact of a tax position, if that position is more likely than not to be sustained on examination, based on the technical merits of the position. FIN 48 is effective as of the beginning of the first annual reporting period that begins after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our results of operations and financial condition.

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

Not applicable.

**Item 8. Financial Statements and Supplementary Data.**

See Index to Financial Statements at page 86 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*

As of the end of the period covered by 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 Rule 13a-15 promulgated under the Securities Exchange Act of 1934. Based upon that evaluation, our 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 our 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



**Table of Contents**

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 ourself.

*Changes in Internal Control over Financial Reporting*

No changes were made in our internal control over financial reporting subsequent to the date of our Chief Executive Officer's and Chief Financial Officer's evaluation that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Management's Report on Internal Controls over Financial Reporting*

Our 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.

**Table of Contents**

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, 2006. 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, 2006, 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 76.

**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, 2006, 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, 2006, 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, 2006, 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, 2006 of the Company and our report dated March 12, 2007 expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's adoption of Statement of Financial Accounting Standards No. 123 Revised, Share-Based Payment on January 1, 2006.

/s/ DELOITTE & TOUCHE LLP

Certified Public Accountants

Miami, Florida

March 12, 2007

**Table of Contents**

**Item 9B. Other Information.**

Not applicable.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

The information concerning executive officers required by Item 10 is contained in the discussion entitled Executive Officers of the Registrant in Part I hereof. All other information required by Item 10 is incorporated by reference to our Proxy Statement for our 2007 Annual Meeting of Stockholders.

**Item 11. Executive Compensation.**

The information required by Item 11 is incorporated by reference to our Proxy Statement for our 2007 Annual Meeting of Stockholders.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by Item 12 is incorporated by reference to our Proxy Statement for our 2007 Annual Meeting of Stockholders.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by Item 13 is incorporated by reference to our Proxy Statement for our 2007 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 2007 Annual Meeting of Stockholders.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

**(a)(1) Financial Statements**

See Index to Financial Statements at page 86 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**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
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. 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**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
10.2	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).
10.3	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).
10.4	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).
10.5	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).
10.6	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).
10.7	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).
10.8	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).
10.9	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**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17	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	Incorporated by reference to Exhibit 10.3 of Noven's Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).

provisions omitted pursuant to Rule 24b-2).

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
10.18	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).
10.19	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).
10.20	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).
10.21	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).
10.22	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).
10.23	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).
10.24	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).
10.25	Agreement between Shire Pharmaceuticals Ireland Limited and Noven dated March 6, 2006.**	Incorporated by reference to Exhibit 10.27 of Noven's Form 10-K for the year ended December 31, 2005 (File No. 0-17254).



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
10.26	Agreement between Noven and P&G Pharmaceuticals, Inc. dated April 28, 2003 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.29 of Noven's Form 10-K for the year ended September 30, 2003 (File No. 0-17254).
10.27	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).
10.28	Termination Agreement between Noven and Endo Pharmaceuticals Inc. effective as of December 31, 2005 (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, 2005 (File No. 0-17254).
10.29	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).
10.30	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).
10.31	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).
10.32	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).
10.33	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



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
10.34	Noven Pharmaceuticals, Inc. Nonqualified Deferred Compensation Plan, as amended and restated September 15, 2006.*	Incorporated by reference to Exhibit 10.1 of Noven's Form 10-Q for the quarter ended September 30, 2006 (File No. 0-17254).
10.35	Form of Stock Appreciation Rights Agreement (Employee).*	Incorporated by reference to Exhibit 10.1 of Noven's Form 10-Q for the quarter ended March 31, 2006 (File No. 0-17254).
10.36	Form of Restricted Stock Agreement.*	Incorporated by reference to Exhibit 10.1 of Noven's Form 8-K dated May 22, 2006 (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.***	Furnished 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	Furnished herewith.

the Sarbanes-Oxley Act of 2002.\*\*\*

- \* 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.
- \*\*\* Pursuant to Item 601(b) (32) of Regulation S-K, this exhibit is furnished rather than filed with this Annual Report on Form 10-K.



**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 12, 2007

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 12, 2007
By: /s/ Diane M. Barrett  Diane M. Barrett (Vice President & Chief Financial Officer)	Principal Financial  and Accounting Officer	March 12, 2007
By: /s/ Sidney Braginsky  Sidney Braginsky	Director	March 12, 2007
By: /s/ John G. Clarkson, M.D.  John G. Clarkson, M.D.	Director	March 12, 2007
By: /s/ Donald A. Denkhous  Donald A. Denkhous	Director	March 12, 2007
By: /s/ Pedro P. Granadillo  Pedro P. Granadillo	Director	March 12, 2007
By: /s/ Robert G. Savage  Robert G. Savage	Director	March 12, 2007
By: /s/ Wayne P. Yetter	Director	March 12, 2007



**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<b>NOVEN PHARMACEUTICALS, INC.</b>	
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	87
FINANCIAL STATEMENTS	
<u>Balance Sheets as of December 31, 2006 and 2005</u>	88
<u>Statements of Operations for the years ended December 31, 2006, 2005 and 2004</u>	89
<u>Statements of Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004</u>	90
<u>Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004</u>	91
Notes to Financial Statements	92
<b>VIVELLE VENTURES, LLC</b> <b>(d/b/a NOVOGYNE PHARMACEUTICALS)</b> <b>(a significant unconsolidated joint venture)</b>	
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	129
FINANCIAL STATEMENTS	
<u>Balance Sheets as of December 31, 2006 and 2005</u>	130
<u>Statements of Operations for the years ended December 31, 2006, 2005 and 2004</u>	131
<u>Statements of Members' Capital for the years ended December 31, 2006, 2005 and 2004</u>	132
<u>Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004</u>	133
Notes to Financial Statements	134

**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, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. 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, 2006, 2005, and 2004. Noven's equity in Vivelle Ventures LLC of \$23,296,000 and \$23,243,000 at December 31, 2006 and 2005, respectively, and Noven's share of that joint venture's income of \$28,632,000, \$24,655,000 and \$17,641,000 for the years ended December 31, 2006, 2005, 2004, 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 2006, 2005, and 2004, 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, 2006 and 2005 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, Noven changed its method of accounting for stock-based compensation in accordance with Statement of Financial Accounting Standards No. 123 Revised, Share-Based Payment on January 1, 2006.

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, 2006, 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 12, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Certified Public Accountants

Miami, Florida

March 12, 2007

**Table of Contents****NOVEN PHARMACEUTICALS, INC.**

## Balance Sheets

December 31, 2006 and 2005

(in thousands, except share data)

	2006	2005
Assets		
Current Assets:		
Cash and cash equivalents	\$ 9,144	\$ 66,964
Short-term investments available-for-sale, at fair value	144,455	17,900
Trade receivable (less allowance for doubtful accounts of \$67 in 2006 and \$53 in 2005)	5,038	2,919
Milestone payment receivable Shire	25,000	
Accounts receivable Novogyne, net	7,693	8,912
Inventories	8,651	7,861
Net deferred income tax asset, current portion	4,400	6,000
Prepaid income taxes	3,416	7,697
Prepaid and other current assets	2,410	1,357
	210,207	119,610
Property, plant and equipment, net	37,010	34,455
Other Assets:		
Investment in Novogyne	23,296	23,243
Net deferred income tax asset	8,308	6,373
Patent development costs, net	2,317	2,211
Deposits and other assets	227	18
	34,148	31,845
	\$ 281,365	\$ 185,910
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,765	\$ 5,812
Capital lease obligation current portion	109	121
Accrued liability Shire	419	5,488
Accrued compensation and related liabilities	5,308	5,771
Other accrued liabilities	2,085	2,124
Deferred rent credit	89	89
Deferred contract revenues	1,527	1,481
Deferred license revenues current portion	15,084	7,602
	29,386	28,488
Long-Term Liabilities:		
Capital lease obligation	279	
Deferred rent credit	659	748
Deferred license revenues	74,188	16,053
Deferred compensation liability	178	

Commitments and Contingencies (Note 6 and 15)	104,690	45,289
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 24,661,169 in 2006 and 23,617,221 in 2005	2	2
Additional paid-in capital	109,912	89,846
Retained earnings	66,761	50,773
	176,675	140,621
	\$ 281,365	\$ 185,910

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

**Table of Contents****NOVEN PHARMACEUTICALS, INC.**

## Statements of Operations

Years Ended December 31, 2006, 2005 and 2004

(in thousands, except per share amounts)

	2006	2005	2004
Revenues:			
Product revenues Novogyne:			
Product sales	\$ 19,714	\$ 19,910	\$ 18,798
Royalties	6,845	6,444	5,204
Total product revenues Novogyne	26,559	26,354	24,002
Product revenues third parties	21,767	14,097	12,869
Total product revenues	48,326	40,451	36,871
Contract and license revenues:			
Contract	1,966	2,528	5,021
License	10,397	9,553	3,999
Contract and license revenues	12,363	12,081	9,020
Net revenues	60,689	52,532	45,891
Expenses:			
Cost of products sold Novogyne	14,102	13,547	11,413
Cost of products sold third parties	22,406	20,500	9,101
Research and development	11,454	13,215	9,498
Marketing, general and administrative	21,701	16,915	17,271
Total expenses	69,663	64,177	47,283
Loss from operations	(8,974)	(11,645)	(1,392)
Equity in earnings of Novogyne	28,632	24,655	17,641
Interest income, net	4,272	2,242	999
Income before income taxes	23,930	15,252	17,248
Provision for income taxes	7,942	5,280	6,024
Net income	\$ 15,988	\$ 9,972	\$ 11,224

Basic earnings per share	\$ 0.67	\$ 0.42	\$ 0.48
Diluted earnings per share	\$ 0.66	\$ 0.42	\$ 0.46
Weighted average number of common shares outstanding:			
Basic	23,807	23,566	23,332
Diluted	24,252	23,981	24,305

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



**Table of Contents****NOVEN PHARMACEUTICALS, INC.**

Statements of Stockholders' Equity

Years Ended December 31, 2006, 2005 and 2004

(in thousands)

	Common Stock		Additional	Retained	Total
	Shares	Amount	Paid-in Capital	Earnings	
Balance at December 31, 2003	22,722	\$ 2	\$ 79,244	\$ 29,577	\$ 108,823
Issuance of shares pursuant to employee equity plan, net	757		5,924		5,924
Issuance of stock to outside directors	2		34		34
Tax benefit from exercise of employee equity grants			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 employee equity plan, net	136		1,290		1,290
Tax benefit from exercise of employee equity grants			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
Issuance of shares pursuant to employee equity plan, net	1,040		13,224		13,224
Stock-based compensation expense and issuance of shares to outside directors	4		3,286		3,286
Tax benefit from exercise of employee equity grants			3,556		3,556
Net income				15,988	15,988
Balance at December 31, 2006	24,661	\$ 2	\$ 109,912	\$ 66,761	\$ 176,675

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

**Table of Contents****NOVEN PHARMACEUTICALS, INC.**

## Statements of Cash Flows

Years Ended December 31, 2006, 2005 and 2004

(in thousands)

	2006	2005	2004
Cash flows from operating activities:			
Net income	\$ 15,988	\$ 9,972	\$ 11,224
Adjustments to reconcile net income to net cash flows provided by operating activities:			
Depreciation, amortization and certain other noncash items	4,429	3,126	3,222
Write-off of fentanyl inventories deemed non-saleable		9,475	
Stock based compensation expense	3,286		
Income tax benefits on exercise of stock options	3,556	281	3,034
Excess tax deduction from exercise of stock options	(2,590)		
Deferred income tax (benefit) expense	(335)	2,566	5,236
Recognition of deferred license revenues	(10,397)	(9,553)	(3,999)
Equity in earnings of Novogyne	(28,632)	(24,655)	(17,641)
Distributions from Novogyne	26,368	26,187	18,083
Changes in operating assets and liabilities:			
(Increase) decrease in trade receivable, net	(2,119)	2,476	(1,586)
Increase in milestone payment receivable Shire	(25,000)		
Decrease (increase) in accounts receivable Novogyne, net	1,219	1,186	(3,778)
Increase in inventories	(790)	(1,348)	(10,788)
Decrease (increase) in prepaid income taxes	6,492	3,105	(5,497)
Increase in prepaid and other current assets	(1,053)	(119)	(173)
(Increase) decrease in deposits and other assets	(15)	3	(7)
(Decrease) increase in accounts payable and accrued expenses	(1,047)	(6,364)	8,206
(Decrease) increase in accrued liability Shire	(5,069)	(5,099)	10,497
(Decrease) increase in accrued compensation and related liabilities	(463)	9	2,028
Decrease in other accrued liabilities	(39)	(891)	(575)
Increase (decrease) in deferred contract revenue, net	46	(595)	1,304
Increase in deferred license revenue	76,000		6,500
Increase in deferred compensation	178		
Amounts reimbursable to Shire and offset against deferred license revenue related to Daytrana approval	14	(5,877)	(13,421)
Cash flows provided by operating activities	60,027	3,885	11,869
Cash flows from investing activities:			
Purchases of property, plant and equipment, net	(6,261)	(13,669)	(6,529)
Payments for patent development costs, net	(616)	(486)	(586)
Purchase of company-owned life insurance	(185)		
Purchases of short-term investments	(1,298,424)	(516,505)	
Proceeds from sale of short-term investments	1,171,975	498,605	
Cash flows used in investing activities	(133,511)	(32,055)	(7,115)
Cash flows from financing activities:			
Issuance of common stock from exercise of stock options	13,224	1,290	5,924
Excess tax benefit from exercise of stock options	2,590		

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-K

Payments under capital leases	(150)	(114)	(101)
Cash flows provided by financing activities	15,664	1,176	5,823
Net (decrease) increase in cash and cash equivalents	(57,820)	(26,994)	10,577
Cash and cash equivalents, beginning of year	66,964	93,958	83,381
Cash and cash equivalents, end of year	\$ 9,144	\$ 66,964	\$ 93,958

*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, including specific estimates related to (a) separating deliverables related to collaborative agreements into separate units of accounting and then recognizing revenues for those separated units at their fair value as earned, (b) 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, (c) contract revenues consisting of development fees and milestone payments that require estimates of proportional performance of work completed, (d) estimating allowances for returns for product that has been recalled or that Noven believes is probable of being recalled, (ii) determination of the fair value of employee stock options to determine compensation expense, (iii) the valuation of inventories and the allocation of overhead expenses, (iv) whether or not to capitalize pre-launch inventories and (v) determination of the net realizable value of the net deferred tax asset, estimation of the effective tax rate and income and other tax accruals.

**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 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, 2006 and 2005, consisted primarily of overnight money market accounts, time deposits, commercial paper 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 . Although the contractual maturities of the auction rate securities and the variable rate demand bonds 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. Noven does not intend to hold these securities for longer than one year. 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. As of December 31, 2006 and 2005, the cost of all short-term investments approximated fair value. No unrealized gains and losses have been recognized for the years ended December 31, 2006 and 2005, respectively. Realized gains and losses and interest and dividends are included in interest income or interest expense, as appropriate.

**Table of Contents**

As of December 31, 2006 and 2005, Noven's short-term investments consisted of the following (amounts in thousands):

	Fair Value	
	2006	2005
Short-Term:		
Tax-exempt variable rate demand bonds	\$ 60,360	\$ 2,900
Tax-exempt municipal auction rate securities	67,790	15,000
Taxable municipal auction rate securities	2,900	
Dividend preferred auction rate securities	2,500	
Commercial paper	10,905	
	\$ 144,455	\$ 17,900

**INVENTORIES:**

Inventories consist primarily of raw materials, work in process and finished goods for Noven's 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. Certain raw materials and components used in the manufacture of its products (including essential polymer adhesives and other critical components) are available from limited sources, and in some cases, a single source. In addition, the Drug Enforcement Agency (DEA) controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing.

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.

Shire plc (Shire) retains title to the active methylphenidate ingredient (AMI) in Daytrana. AMI is not included in Daytrana product revenues or in Noven's cost of products sold. Noven records AMI maintained at its manufacturing facility as consignment inventory and bears certain manufacturing risks of loss related to the AMI. These risks include the contractual obligation of Noven to reimburse Shire for the cost of AMI if Noven does not meet certain minimum yields of the finished product. During 2006, Noven used \$4.0 million of AMI in the finished product and reimbursed Shire approximately \$0.4 million for excess AMI used in production, which amount is included in cost of products sold. Noven had \$1.0 million of consignment AMI inventory on hand at December 31, 2006, which is not reflected in the table below.

**Table of Contents**

*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*

Pre-launch inventories consist primarily of Noven's branded or generic product candidates prior to the date that Noven anticipates that such products will receive final marketing approval from the United States Food and Drug Administration ( FDA ) or the satisfactory resolution of patent infringement litigation, or any other circumstances that will make Noven's product candidates commercially viable. 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.

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 Noven anticipates 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

**Table of Contents**

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, 2006 and 2005 (in thousands):

	December 31, 2006			December 31, 2005		
	Commercial	Pre-Launch	Total	Commercial	Pre-Launch	Total
Finished goods	\$ 893	\$	\$ 893	\$ 760	\$	\$ 760
Work in progress	2,851		2,851	1,278	1,004	2,282
Raw materials	4,907		4,907	3,422	1,397	4,819
	\$ 8,651	\$	\$ 8,651	\$ 5,460	\$ 2,401	\$ 7,861

Pre-launch inventories as of December 31, 2005 consisted of Noven's Daytran product, which received final approval from the FDA in April 2006 and was commercially launched in June 2006.

**COST OF PRODUCTS SOLD:**

Direct and indirect costs of manufacturing are included in cost of products sold. Indirect costs include overhead costs, which consist of salaries and benefits, supplies and tools, equipment costs, depreciation and insurance costs and represent a substantial portion of Noven's inventory production costs. Noven uses a standard costing system to estimate its actual FIFO cost of inventory at the end of each reporting period. Unallocated overhead costs are recognized as an expense in the period in which they are incurred.

**PROPERTY, PLANT AND EQUIPMENT:**

Property, plant and equipment consists of the following at December 31, 2006 and 2005 (in thousands, except estimated useful lives):

	2006	2005	Estimated
			Useful Lives (in years)
Land	\$ 2,540	\$ 2,540	
Building and improvements	3,288	3,231	40
Leased property and leasehold improvements	21,529	19,231	10-31
Manufacturing and other equipment	24,036	21,628	3-10
Furniture	2,339	1,734	10
Software and software development costs	5,101	4,238	3
	58,833	52,602	
Less accumulated depreciation and amortization	(21,823)	(18,147)	
	\$ 37,010	\$ 34,455	



**Table of Contents**

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. During 2006, 2005, and 2004 depreciation expense was \$4.0 million, \$2.7 million, and \$2.3 million, respectively.

**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 from the time the preliminary project stage is completed until the software is ready for use. 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, 2006 and 2005, approximately \$0.9 million and \$1.2 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.

**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. Amortization expense was \$0.5 million for 2006 and \$0.4 million for each of 2005 and 2004.

**INCOME TAXES:**

Noven accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* ( SFAS 109 ). SFAS 109 provides that income taxes are accounted for using an asset and liability method

**Table of Contents**

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. In addition, if Noven is assessed interest and/or penalties by governing jurisdictions, Noven includes those amounts in its tax provision. In July 2006, the FASB issued FIN 48 to clarify the accounting for uncertainties related to income taxes that are recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 is effective as of the beginning of the first annual reporting period that begins after December 15, 2006. Noven is evaluating the impact of adopting FIN 48 on Noven's results of operations and financial condition (see Note 7).

**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 when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. Receivables for insurance recoveries related to litigation under Noven's third party insurance policies are recorded when it is probable that recovery will be realized. 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 that will be incurred and expected insurance recovery, if any. Accruals for tax contingencies require Noven to make assumptions based upon management's best estimate of possible assessments by taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances (see Notes 7 and 15).

**REVENUE RECOGNITION:**

Substantially all of Noven's product revenues were for sales to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis Pharma), Shire and sanofi-aventis (Aventis) (see Notes 4 and 5). 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

**Table of Contents**

are not determinable, Noven records the adjustments on a cash basis. These amounts are included in product revenues.

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

Noven enters into certain contracts that have various terms and conditions that may have multiple revenue characteristics, including license revenues, contract revenues, product sales and manufacturing revenues. As prescribed by Emerging Issues Task Force 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 the Securities and Exchange Commission (SEC) Staff Accounting Bulletin Topic 13, Revenue Recognition (SAB 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

**Table of Contents**

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.

Product revenues are net of an allowance for returns, if any. 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 believes that its revenue recognition policy is in compliance with the requirements of SEC Staff Accounting Bulletin Topic 13.

**VENDOR DISCOUNTS:**

Noven receives purchase-volume-related discounts and rebates from vendors in the normal course of business. Management uses projected purchase volumes to estimate accrual rates, validates those projections based on actual purchase trends and applies those rates to actual purchase volumes to determine the amount of funds accrued by Noven and receivable from the vendor. Amounts accrued could be impacted if actual purchase volumes differ from projected purchase volumes. Purchase-volume-related discounts or rebates are treated as a reduction of inventory cost or cost of products sold, depending on whether the related inventory is on-hand or has been previously sold.

**RESEARCH AND DEVELOPMENT COSTS:**

Research and development costs include costs of internally generated research and development activities and costs associated with work performed under agreements with third parties. Research and development costs are expensed as incurred and include direct and allocated expenses, 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.

**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 Noven issues were exercised or converted into common stock. Common stock equivalents are not included in the diluted earnings per share calculation if the effect of

**Table of Contents**

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, 2006, 2005 and 2004 was 421,813, 2,019,863, and 1,360,983 shares, respectively, which amounts represent out-of-the-money stock options.

**COMPREHENSIVE INCOME:**

For the years ended December 31, 2006, 2005 and 2004, total comprehensive income was equal to net income.

**EMPLOYEE STOCK PLANS:**

On January 1, 2006, Noven adopted the provisions of, and began accounting for stock-based compensation in accordance with, Statement of Financial Accounting Standards No. 123 Revised, Share Based Payment (SFAS 123(R)). Under the fair value recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Noven elected the modified-prospective method, under which prior periods are not revised for comparative purposes. The valuation provisions of SFAS 123(R) apply to new grants and to grants that were outstanding as of the effective date and are subsequently modified. Estimated compensation for grants that were outstanding as of the effective date will be recognized over the remaining service period using the grant date fair value previously calculated for the SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123) pro forma disclosures requisite.

Noven currently uses the Black-Scholes option pricing model to determine the fair value of stock options and stock-settled stock appreciation rights (SSARs). The grant date fair value of stock-based payment awards using an option-pricing model is affected by Noven's stock price as well as assumptions regarding a number of complex and subjective variables. These variables include Noven's expected stock price volatility over the expected term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, estimated forfeitures of awards and expected dividends.

Noven estimates the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as described in the SEC's Staff Accounting Bulletin Topic 14: Share-Based Payment (SAB 107) (SAB 107). Noven estimates the volatility of common stock by using a combination of both historical and implied volatility based on an equal weighting of each, as management believes it is the expected volatility that marketplace participants would likely use in determining an exchange price for an option. Noven bases the risk-free interest rate that Noven uses in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. Noven does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model. Noven estimates forfeitures based on historical data at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. All stock-based payment

**Table of Contents**

awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. The fair value of each SSAR/option granted during 2006, 2005 and 2004 is estimated to be \$10.94, \$8.64 and \$13.10, respectively, on the date of the grant using the Black-Scholes option-pricing model with the assumptions below:

	2006	2005	2004
Volatility	49.2%	69.0%	69.0%
Risk free interest rate	4.67%	4.30%	3.49%
Expected life (years)	5	5	5

Total pre-tax stock-based compensation recognized in Noven's statement of operations for the period ended December 31, 2006 was \$3.3 million, of which \$2.5 million was recognized in marketing, general and administrative and \$0.4 million was recognized in each of research and development and cost of products sold, respectively. The tax benefit recognized related to compensation expense was \$0.9 million. There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the year ended December 31, 2006.

Prior to the adoption of SFAS 123(R), Noven presented all tax benefits for deductions resulting from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options as operating cash flows on its statement of cash flows. SFAS 123(R) requires the benefits of tax deductions in excess of those recognized in conjunction with compensation expense, to be reported as a financing cash flow, rather than as an operating cash flow. This requirement has the effect of reducing net operating cash flows and increasing net financing cash flows in periods in and after adoption. However, under this requirement, total cash flow remains unchanged from what would have been reported under prior accounting rules. Cash received from options exercised under all share-based payment arrangements for the period ended December 31, 2006, 2005 and 2004 was \$13.2 million, \$1.3 million and \$5.9 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled \$3.6 million, \$0.3 million and \$3.0 million for the periods ended December 31, 2006, 2005 and 2004, respectively, of which \$2.6 million was reported as a financing cash flow for the period ended December 31, 2006. There were no amounts reported as financing cash flow for the periods ended December 31, 2005 and 2004. The total intrinsic value of all option exercises for each of the years ended December 31, 2006, 2005 and 2004 were \$10.5 million, \$0.9 million and \$9.8 million, respectively.

At December 31, 2006, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and nonvested shares (restricted stock), as determined in accordance with SFAS 123(R), is approximately \$8.3 million before the effect of income taxes, of which \$3.5 million, \$2.4 million, \$1.6 million and \$0.8 million is expected to be incurred in 2007, 2008, 2009 and 2010, respectively.

**Table of Contents**

In accordance with the modified prospective transition method, Noven's financial statements for prior periods have not been restated and do not include the impact of SFAS 123(R). Accordingly, no compensation expense related to stock option awards was recognized in 2005 or 2004, as all stock options granted had an exercise price equal to the fair market value of the underlying common stock on the date of grant. The following table shows the effect on net income and income per share as if the fair-value-based method of accounting had been applied to all outstanding and unvested stock option awards prior to adoption for SFAS 123(R) (in thousands, except per share amounts):

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

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 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 (the "1999 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.

**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 13 for disclosures about geographic areas and

**Table of Contents**

major customers in accordance with Statement of Financial Accounting Standards No. 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, short-term investments, accounts receivable, accounts payable and accrued expenses reasonably approximate fair value because of the short term nature of these items.

**CONCENTRATIONS OF CREDIT RISK:**

Noven's customers currently consist of Novogyne, Novartis Pharma, Shire 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.

**RECLASSIFICATION:**

Certain reclassifications have been made to the prior years' statement of cash flows to conform to the current year's presentation.

**RECENT ACCOUNTING PRONOUNCEMENTS:**

In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements ( SFAS 157 ). This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The adoption of SFAS 157 is not expected to have a material impact on Noven's results of operations or financial condition.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ( SAB 108 ), which added Section N to Topic 1, Financial Statements, of the Staff Accounting Bulletin Series effective the fiscal year ending after November 15, 2006. Section N provides guidance on the consideration of the effects of prior year misstatements when quantifying current year financial statement misstatements for the purpose of materiality assessment. The SEC concluded in SAB 108 that a registrant's materiality evaluation of an identified unadjusted error should quantify the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements. If either the carryover or reversing effects of prior year misstatements is material, the misstatements should be corrected in the current year. If correcting an error in the current year for prior year misstatements causes the current year to be materially misstated, the prior year financial statements should be corrected, even though such revision previously was and



**Table of Contents**

continues to be immaterial to the prior year financial statements. SAB 108 was adopted on December 31, 2006 and its adoption did not have a material impact on Noven's results of operations or financial condition.

In July 2006, the FASB issued Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48) to clarify the accounting for uncertainties related to income taxes that are recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation requires financial statement recognition of the impact of a tax position, if that position is more likely than not to be sustained on examination, based on the technical merits of the position. FIN 48 is effective as of the beginning of the first annual reporting period that begins after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. Noven is currently evaluating the impact of adopting FIN 48 on its results of operations and financial condition.

**3. CASH FLOW INFORMATION:**

Cash payments for income taxes were \$0.8 million, \$1.6 million and \$5.4 million in 2006, 2005, and 2004, respectively. Cash payments for interest were \$15,000, \$12,000, and \$18,000 in 2006, 2005 and 2004, 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 2006, 2005 and 2004 Novogyne paid \$2.2 million, \$1.5 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 \$3.6 million, \$0.3 million and \$3.0 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 2006, 2005 and 2004, respectively.

*Non-cash Investing Activities*

In 2006 and 2004, Noven entered into capital lease obligations totaling \$0.4 and \$0.3 million for new equipment, respectively.

In 2005 Noven recorded approximately \$0.9 million in leasehold improvements as a deferred rent credit relating to landlord-funded leasehold improvements. See Note 6 Operating and Capital Leases.

**Table of Contents**

## 4. 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 (\$0.7 million as of December 31, 2006), 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, 2006 and 2005, the carrying amount of the leased property and deferred revenues was \$3.8 million and \$4.1 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 granted Novartis Pharma the right to market 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 that was paid by Noven to Aventis, and by Novogyne to Noven, was \$40.0 million. 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 Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market a generic fentanyl patch. 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 technology. Noven's agreement provides that Endo would fund and manage clinical development of those compounds proceeding into clinical trials.

**Table of Contents**

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. 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. In addition, Noven deemed the entire \$14.0 million of fentanyl patch inventories on hand at that time 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, and has granted Endo a right of first negotiation with respect to any reformulated fentanyl patch that it may develop. Noven's decision to proceed with the fentanyl project is expected to depend upon, among other things, the expense, the timeline and risk of seeking FDA approval, and the size and sustainability of the United States market opportunity at the time Noven's product would be launched. 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.

Noven and Endo continue to proceed with other areas of their development collaboration that are unrelated to fentanyl.

**SHIRE COLLABORATION**

Noven has developed a once-daily transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder called Daytrana. In the first quarter of 2003 Noven licensed to Shire the exclusive global rights to market Daytrana for payments by Shire of up to \$150.0 million. In consideration for the transaction Shire agreed to pay Noven as follows: (i) \$25.0 million was paid upon closing of the transaction in April 2003; (ii) \$50.0 million was paid in April 2006 upon receipt of final marketing approval 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 Daytrana net sales, respectively. Shire launched the product in June 2006. Noven is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is Noven's current best estimate of the end of the useful economic life of the product. Shire's net sales of Daytrana exceeded the threshold for the first sales

**Table of Contents**

milestone in the fourth quarter of 2006 and, accordingly, Noven received a \$25.0 million payment from Shire in the first quarter of 2007. During 2006, Noven recognized \$5.9 million in license revenues related to the Shire collaboration. Noven also manufactures and supplies finished product for Shire and during 2006, Noven's product sales of Daytrana to Shire were \$8.6 million.

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. Beginning in the fourth quarter of 2003, Noven recorded 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 were recorded as a reduction of a portion of the \$25.0 million nonrefundable deferred license revenue previously received from Shire. 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 2006, 2005, or 2004, although the reimbursements or amounts reimbursable to Shire reduced Noven's cash position and also reduced the amount of deferred revenues that Noven is currently recognizing related to the original \$25.0 million up-front payment. Upon obtaining Daytrana regulatory approval in April 2006, \$4.8 million remained in deferred license revenues of the original \$25.0 million, which is currently being recognized on a straight-line basis as license revenue from the date of approval through the first quarter of 2013.

In addition to Noven's agreements with Shire related to Daytrana in June 2004 Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD, and in July 2006, Noven and Shire amended this agreement. Under the amended agreement, Shire paid Noven a non-refundable \$1.0 million in August 2006, in exchange for the option of purchasing, for an additional \$5.9 million, the exclusive developmental rights to the product. The amended agreement further provides that Noven will perform certain early-stage development activities which were previously to be performed by Shire. Upon Noven's completion of such development activities, Shire has the option to pay Noven the \$5.9 million to continue exclusive development of the product. If Shire does not exercise this option, rights to further develop the product will revert to Noven. The product entered Phase I clinical development by Noven in December 2006. The \$1.0 million was included in deferred contract revenues on Noven's balance sheet as of December 31, 2006.

**P&G PHARMACEUTICALS COLLABORATION**

In April 2003, Noven established a collaboration with P&G Pharmaceuticals for the development of new prescription patches for Hypoactive Sexual Desire Disorder ( HSDD ).

**Table of Contents**

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. During 2006, 2005 and 2004, Noven earned \$0.9 million, \$0.1 million and \$4.4 million under the P&G Pharmaceuticals collaboration, respectively. In the U.S., P&G Pharmaceuticals withdrew its NDA for Intrinsa in December 2004 based on safety concerns expressed by an FDA Advisory Committee and other factors. P&G Pharmaceuticals has indicated that work on Intrinsa for the U.S. market has been placed on hold while they evaluate alternatives for the project. If P&G Pharmaceuticals is unable to identify a practical strategy to complete development and commercialize the product in the U.S., or if their evaluation of alternatives significantly delays the project, the prospects for Noven's collaboration with P&G Pharmaceuticals will be adversely affected.

**OTHER AGREEMENTS**

Noven has entered into other developmental agreements for feasibility of certain compounds. In 2006, 2005 and 2004 Noven received approximately \$0.2 million, \$1.7 million and \$0.4 million, respectively, related to these agreements. During 2006, Noven also recognized a \$1.0 million one-time payment from a third party for a license to certain Noven patents due to Noven having no continuing involvement nor Noven having any future economic benefit related to the license. Noven has also established additional collaborations with third parties relating to the development of transdermal products outside of the ADHD and HT categories. Details relating to these collaborations have not been disclosed for competitive, confidentiality and other reasons.

**5. 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 in Novogyne, Novartis granted an exclusive sublicense to Novogyne of a license agreement with Noven (see Note 4). 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.

**Table of Contents**

The summarized Statements of Operations of Novogyne for the years ended December 31, 2006, 2005 and 2004 are as follows (in thousands):

	2006	2005	2004
Gross revenues	\$ 154,901	\$ 136,901	\$ 124,791
Sales allowances	17,226	14,408	13,154
Sales returns allowances	5,732	936	6,224
Sales allowances and returns	22,958	15,344	19,378
Net revenues	131,943	121,557	105,413
Cost of sales	30,149	28,696	27,755
Selling, general and administrative expenses	37,318	35,568	35,624
Income from operations	64,476	57,293	42,034
Interest income	841	461	191
Net income	\$ 65,317	\$ 57,754	\$ 42,225
Noven's equity in earnings of Novogyne	\$ 28,632	\$ 24,655	\$ 17,641

The activity in the Investment in Novogyne account for the years ended December 31, 2006, 2005 and 2004 is as follows (in thousands):

	2006	2005	2004
Investment in Novogyne, beginning of year	\$ 23,243	\$ 26,233	\$ 28,368
Equity in earnings of Novogyne	28,632	24,655	17,641
Cash distributions from Novogyne	(26,368)	(26,187)	(18,083)
Non-cash distribution from Novogyne	(2,211)	(1,458)	(1,693)
Investment in Novogyne, end of year	\$ 23,296	\$ 23,243	\$ 26,233

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 reported above represented a \$2.2 million, \$1.5 million and \$1.7 million tax payment in April 2006, 2005 and 2004, respectively, 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.

**Table of Contents**

The summarized Balance Sheets of Novogyne at December 31, 2006 and 2005 are as follows (in thousands):

	2006	2005
Current assets	\$ 29,447	\$ 22,313
Insurance receivable	7,299	3,511
Intangible assets	26,263	32,442
Total long-term assets	33,562	35,953
Total assets	63,009	58,266
Product liability reserve	9,629	4,945
Allowance for returns	7,938	6,168
Other liabilities	8,943	10,341
Total liabilities (all of which are current)	26,510	21,454
Members' capital	\$ 36,499	\$ 36,812

The activity for the allowance for returns for the three years ended December 31, 2006 is as follows in thousands):

Balance January 1, 2004	\$ 14,240
Expense related to expired product-current year	8,342
Expense related to expired product-prior year	1,227
Expense related to product recalls	(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
Expense related to expired product-current year	4,342
Expense related to expired product-prior year	1,390
Deductions	(3,962)
Balance December 31, 2006	\$ 7,938



**Table of Contents**

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 of these recalls, Novogyne recorded a \$6.5 million estimated returns reserve related to the recalls as of December 31, 2003. Novogyne reversed the remaining recall reserve of \$3.3 million to income in 2004, as the FDA closed out the recall.

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 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 than Noven, and therefore, may be in a better position to be the purchaser if the buy/sell provision is triggered. In addition, this buy/sell provision may have an anti-takeover effect on Noven since a potential acquirer of Noven will face the possibility that Novartis could trigger this provision at any time and thereby require any acquirer to either purchase Novartis' interest in Novogyne or to sell its interest in Novogyne to Novartis.

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

**Table of Contents**

During the years ended December 31, 2006, 2005 and 2004, Noven had the following transactions with Novogyne (in thousands):

	2006	2005	2004
Revenues:			
Trade product	\$ 17,013	\$ 17,787	\$ 15,216
Sample product and other	2,701	2,123	3,582
Royalties	6,845	6,444	5,204
	\$ 26,559	\$ 26,354	\$ 24,002
Reimbursed expenses:			
Services	\$ 20,926	\$ 20,768	\$ 20,014
Product specific marketing expenses	7,850	6,945	7,780
Reimbursed expenses	\$ 28,776	\$ 27,713	\$ 27,794

As of December 31, 2006 and 2005, the Accounts Receivable Novogyne, net is as follows (in thousands):

	2006	2005
Sales of product	\$ 3,795	\$ 4,126
Services provided by Noven	3,057	3,835
Royalty	1,714	1,827
Deferred profit on Novogyne inventory and other	(873)	(876)
	\$ 7,693	\$ 8,912

## 6. 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

**Table of Contents**

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 each of the years ended December 31, 2006 and 2005.

Lease expense under operating leases, including rent expense related to the Industrial Long-Term Lease described above, was approximately \$1.2 million, \$1.1 million and \$0.5 million for the years ended December 31, 2006, 2005 and 2004, respectively.

The future minimum rental payments required under noncancelable operating and capital leases as of December 31, 2006 are as follows (in thousands):

	Operating Leases	Capital Leases
2007	\$ 1,050	\$ 142
2008	1,017	154
2009	1,002	129
2010	913	8
2011	932	8
Thereafter	2,851	17
Total lease obligation	\$ 7,765	458
Less: portion representing interest		(70)
Capital lease obligation		388
Less: current portion		(109)
Capital lease obligation, net of current portion		\$ 279

**Table of Contents**

## 7. INCOME TAXES:

The provision (benefit) for income taxes in 2006, 2005 and 2004 consists of (in thousands):

	2006	2005	2004
Current income taxes:			
Federal	\$ 7,123	\$ 2,347	\$ 638
State	1,154	367	150
	8,277	2,714	788
Deferred income tax (benefit) expense:			
Federal	(241)	2,291	4,322
State	(94)	275	914
	(335)	2,566	5,236
Provision for income taxes	\$ 7,942	\$ 5,280	\$ 6,024

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):

	2006	2005
Deferred income tax assets:		
Deferred license revenue	\$ 6,234	\$ 7,732
Joint venture interest	3,451	2,499
Inventory adjustments and reserves	2,153	2,268
Deferred profit on sales to Novogyne	334	332
Deferred rent credit	433	
Non-qualified stock options	712	
Other	585	467
Total deferred income tax assets	13,902	13,298
Deferred income tax liabilities:		
Basis difference in fixed assets	(1,194)	(925)
Net deferred income tax asset	\$ 12,708	\$ 12,373

Realization of the net deferred income tax asset of \$12.7 million and \$12.4 million at December 31, 2006 and 2005, 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, 2006 and 2005.

**Table of Contents**

The income tax benefits derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options in excess of any amounts previously classified as a deferred tax asset, when realized, are credited to additional paid-in capital. For the years ended December 31, 2006, 2005 and 2004, Noven credited \$3.6 million, \$0.3 million and \$3.0 million, respectively, to additional paid-in capital related to the excess tax benefits from the exercise of stock options. Of the \$3.6 million credited to additional paid-in capital in 2006, \$1.0 million was classified as cash provided by operating activities in the statement of cash flows, representing that portion of cash provided by operating activities computed as if FAS 123(R) had always been applied for recognition purposes, and the remaining \$2.6 million was classified as cash provided by financing activities.

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

	2006		2005		2004	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	\$ 8,375	35.0	\$ 5,338	35.0	\$ 6,037	35.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	690	2.9	323	2.1	691	4.0
Non-taxable interest income	(1,323)	(5.5)	(385)	(2.5)		
Non-deductible incentive stock option compensation expense	228	0.9				
Extraterritorial income exclusion			122	0.8	(179)	(1.0)
Research and development expenditures credit			(141)	(0.9)	(135)	(0.8)
Increase (reduction) in IRS audit and state tax contingency accruals			1		(400)	(2.3)
Other	(28)	(0.1)	22	0.1	10	
Income tax expense	\$ 7,942	33.2	\$ 5,280	34.6	\$ 6,024	34.9

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, and then reduced the accrual by \$0.4 million in 2004 and an additional \$0.1 million in 2005. In 2005 Noven paid the IRS for all amounts due, except for \$0.1 million in interest charges, which were paid in January 2006.

**Table of Contents****8. STOCKHOLDERS EQUITY:**

Noven established 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. Prior to January 1, 2006, all awards granted to employees under the 1999 Plan were stock options, with the exception of unrestricted stock awards for a total of 4,534 shares that were granted in 2004. In 2006, Noven began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options. 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 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 equity award granted under the 1999 Plan is exercisable after the period(s) specified in the relevant agreement, and no equity award 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, 2006, there were 2,863,733 stock options and 411,306 SSARs issued and outstanding under the 1999 Plan. Historically, the equity awards 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 requires compensation expense associated with equity awards to 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, 2006, there were no 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.

In May 2006, Noven issued a total of 34,344 shares of restricted stock to its non-employee directors. The grants fall under the definition of nonvested shares under SFAS 123(R). The shares vest over each director's one-year service period, quarterly, beginning with the quarter ended June 30, 2006.

**Table of Contents**

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

	2006		2005		2004	
	Options/ SSARs	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	4,004	\$17.23	3,739	\$17.69	3,919	\$14.51
Granted	411	22.49	557	14.25	1,015	21.70
Exercised	(1,045)	12.77	(137)	9.52	(769)	8.03
Canceled and expired	(95)	18.86	(155)	24.44	(426)	15.52
Outstanding at end of year	3,275	19.26	4,004	17.23	3,739	17.69
Options exercisable at end of year	2,136	20.97	2,871	19.14	1,541	18.35
Shares of common stock reserved	3,428		4,504		4,644	

The following tables summarize information concerning outstanding and exercisable options/SSARs at December 31, 2006 (options and aggregate intrinsic value in thousands):

Range of Exercise Prices	Number Outstanding at Year End	Options/SSARs Outstanding Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 9.08 - 13.12	689	3.4	\$ 11.53	\$ 9,584
13.68 - 17.91	959	4.2	14.78	10,229
18.00 - 24.17	1,214	5.4	22.33	3,791
31.31 - 34.50	404	0.9	33.43	
36.24 - 41.81	9	1.1	38.34	
	3,275			\$ 23,604

**Table of Contents**

Options/SSARs Exercisable			
Range of Exercise Prices	Number Exercisable at Year End	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 9.08 - 13.12	322	\$ 11.90	\$ 4,358
13.68 - 17.91	572	15.35	5,783
18.00 - 24.17	829	22.10	2,780
31.31 - 34.50	404	33.43	
36.24 - 41.81	9	38.34	
	2,136		\$ 12,921

The total fair value of options that vested in each of the years 2006, 2005 and 2004 were \$3.3 million, \$21.2 million and \$6.3 million, respectively. The year 2005 included the acceleration of options with a fair value of \$10.1 million, which reduced future compensation expense by that amount. The following table summarizes the options outstanding, options vested or expected to vest, and options exercisable at December 31, 2006 (options and aggregate intrinsic value in thousands):

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at end of year	3,275	\$ 19.26	4.1	\$ 23,604
Vested or expected to vest at end of year	2,871	\$ 19.42	4.0	\$ 20,115
Exercisable at end of year	2,136	\$ 20.97	3.3	\$ 12,921



**Table of Contents**

The following table summarizes information concerning Noven's restricted stock at December 31, 2006 (shares in thousands):

	Shares	2006 Weighted Average Grant-Date Fair Value \$
Nonvested at December 31, 2005		
Granted	34	17.47
Vested	(26)	17.47
Forfeited		
Nonvested at December 31, 2006	8	\$ 17.47

On November 6, 2001, Noven's Board of Directors adopted a Stockholder Rights Plan under which Noven declared a dividend of one right for each share of common stock outstanding. Prior to the Distribution Date referred to below, the rights will be evidenced by, and trade with, the certificates for the common stock. After the Distribution Date, Noven will mail rights certificates to the stockholders and the rights will become transferable apart from the common stock. Rights will separate from the common stock and become exercisable following (a) the tenth day after a public announcement that a person or group acquired beneficial ownership of 15% or more of Noven's common stock in a transaction or series of transactions not approved by Noven's Board of Directors or (b) the tenth business day (or such later date as may be determined by a majority of the directors) after a person or group announces a tender or exchange offer (with respect to which the Board of Directors does not issue a favorable recommendation), the consummation of which would result in ownership by a person or group of 15% or more of Noven's common stock (in either case, such date is referred to as the Distribution Date). After the Distribution Date, each right will entitle the holder to purchase for \$110 a fraction of a share of Noven's preferred stock with economic terms similar to that of one share of Noven's common stock. In addition, upon the occurrence of certain events, holders of the rights (other than rights owned by an acquiring person or group) would be entitled to purchase either Noven's preferred stock or shares in an acquiring entity at approximately half of market value. The rights will expire on November 6, 2011, and Noven generally will be entitled to redeem the rights at \$0.01 per right at any time prior to the close of business on the tenth day after there has been a public announcement of the beneficial ownership by any person or group of 15% or more of Noven's voting stock, subject to certain exceptions. The plan is intended to protect the interests of Noven's stockholders against certain coercive tactics sometimes employed in takeover attempts. The adoption of the Stockholder Rights Plan could make it more difficult for a third party to acquire a majority of

**Table of Contents**

Noven's common stock in a transaction that does not have the support of Noven's Board of Directors.

**9. DEFERRED COMPENSATION PLAN:**

Effective January 1, 2006, Noven established a deferred compensation plan (the "Plan") available to Noven's officers and members of its Board of Directors. The Plan permits participants to defer receipt of part of their current compensation to a later date as part of their personal retirement or financial planning. Participants may elect to defer, as applicable, portions of their director fees, base salary, bonus, long-term incentive plan awards, and/or restricted stock grants. Participants have an unsecured contractual commitment by Noven to pay amounts due under the Plan. Benefit security for the Plan is provided by a rabbi trust, which is intended to protect participants if Noven is unwilling to pay Plan benefits for any reason other than insolvency or bankruptcy.

The compensation withheld from Plan participants, together with investment income on the Plan, is reflected as a deferred compensation obligation to participants and is classified as a long-term liability in the accompanying balance sheet. The related assets, which are held in the rabbi trust in the form of a company-owned life insurance policy that names Noven as the beneficiary, are classified within other assets in the accompanying balance sheet and are reported at cash surrender value, which was approximately \$0.2 million as of December 31, 2006. At December 31, 2006, the balance of the deferred compensation liability totaled \$0.2 million.

**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 2006, 2005 or 2004.

**11. COST REDUCTION PROGRAM:**

Over the past two years, Noven expanded its facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. In September 2005, the FDA ceased review of Noven's ANDA for its fentanyl product after informing Noven that it did not expect to approve the ANDA. In the third quarter of 2006, Noven implemented a program to reduce overhead associated with this expansion. This program included the elimination of certain employee positions. A pre-tax one-time termination charge of \$0.6 million associated with the elimination of these positions was included in marketing, general and administrative expenses for the period ended December 31, 2006. In addition, Noven incurred an additional \$0.1 million in pre-tax outplacement costs, which was included in marketing, general and administrative expenses in 2006. Noven does not expect any further workforce reductions in connection with this program. Payments made in connection with the

**Table of Contents**

\$0.6 million one-time termination charge as of December 31, 2006 totaled \$0.3 million. Amounts remaining to be paid as of December 31, 2006 totaled \$0.3 million.

## 12. 401(k) SAVINGS PLAN:

On January 1, 1997, Noven established a savings plan under section 401(k) of the Internal Revenue Code (the 401(k) Plan ) covering substantially all employees who have completed three months of service and have reached the age of twenty-one. This plan allows eligible participants to contribute from one to fifteen percent of their current compensation to the 401(k) Plan 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 \$656,000, \$397,000 and \$353,000 to the 401(k) Plan for the years ended December 31, 2006, 2005 and 2004, respectively.

## 13. 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):

	2006	2005	2004
United States	\$ 43,628	\$ 34,546	\$ 28,923
Other countries	17,061	17,986	16,968
Net revenues	\$ 60,689	\$ 52,532	\$ 45,891

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

	2006	2005	2004
Novogyne	\$ 26,559	\$ 26,354	\$ 24,002
Novartis Pharma/Novartis	15,287	16,955	14,721
Shire	14,556		
Endo	303	6,682	853
Other	3,984	2,541	6,315
Net revenues	\$ 60,689	\$ 52,532	\$ 45,891

**Table of Contents**

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

2006	First	Second	Third	Fourth	Full Year
Net revenues	\$ 10,192	\$ 17,547	\$ 15,708	\$ 17,242	\$ 60,689
Gross profit (product revenues less cost of products sold)	2,507	1,417	3,784	4,110	11,818
(Loss) income from operations	(4,168)	(2,868)	(1,870)	(68)	(8,974)
Equity in earnings of Novogyne <sup>1</sup>	4,327	6,762	8,234	9,309	28,632
Net income	\$ 504	\$ 3,333	\$ 5,031	\$ 7,120	\$ 15,988
Basic earnings per share	\$ 0.02	\$ 0.14	\$ 0.21	\$ 0.30	\$ 0.67
Diluted earnings per share	\$ 0.02	\$ 0.14	\$ 0.20	\$ 0.29	\$ 0.66
2005	First	Second	Third	Fourth	Full Year
Net revenues <sup>2</sup>	\$ 11,736	\$ 11,771	\$ 12,240	\$ 16,785	\$ 52,532
Gross profit (loss) (product revenues less cost of products sold) <sup>2</sup>	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 <sup>1</sup>	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

<sup>1</sup> 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.

<sup>2</sup> 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.

**Table of Contents**

## 15. 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 42 to 58 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 six product liability lawsuits 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 Assessments below for a further discussion on related product liability lawsuits.

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

**Table of Contents**

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.

**SUPPLY AGREEMENT:**

Noven's supply agreement with Novogyne for Vivelle® and Vivelle-Dot® patches expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement's commercial terms. There is no assurance that the agreement's non-commercial terms would be enforceable with respect to post-expiration occurrences. A decision to discontinue operating in accordance with the agreement's commercial terms could have a material adverse effect on Noven's financial position, results of operations and cash flows. 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 entered an order 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.

In April 2006, an individual plaintiff and her husband filed a complaint in the United States District Court, District of Minnesota against Noven, Novogyne, Novartis, Wyeth Inc. and Wyeth Pharmaceuticals, Inc. alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including Noven's CombiPatch® product. The plaintiffs claim compensatory and other damages in an unspecified amount.

In July 2006, four complaints were filed in the United States District Court, District of Minnesota against Noven and other pharmaceutical companies by four separate individual plaintiffs, each filing alone or with her husband. Three of the complaints also name Novartis as a defendant, and of these, two name Novogyne as a defendant as well. Each complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle® in one case and CombiPatch® in two of the cases. The plaintiffs in each case claim compensatory and other damages in an unspecified amount. Noven has established an accrual for the expected legal fees related to the cases referenced above, although the amount is not material.



**Table of Contents**

Novartis has advised Noven that Novartis has been named as a defendant in at least 31 lawsuits that include approximately 33 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven's Vivelle-Dot®, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the four lawsuits 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's aggregate limit under its claims-made insurance policy as of December 31, 2006 was \$10.0 million. Novogyne has established reserves in the amount of \$9.6 million with an offsetting insurance recovery of \$7.3 million for expected defense and settlement expenses as well as for estimated future cases alleging use of Noven's HT products. This accrual represents Novartis management's best estimate as of December 31, 2006.

We intend to defend all of the foregoing lawsuits vigorously, but 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, results of operations or cash flows.

**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.

**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 2007 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 \$3.1 million, \$3.6 million and \$3.8 million of bonus expenses in 2006, 2005, and 2004, 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 2006 Noven's performance was less than the company's performance targets, and in

**Table of Contents**

accordance with the plan formula the bonus awards to employees were less than their initial target awards. In 2005 and 2004, 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, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP  
Pricewaterhousecoopers LLP

Florham Park, New Jersey  
February 16, 2007

**Table of Contents**

**Vivelle Ventures LLC**  
**d/b/a Novogyne Pharmaceuticals**  
**Balance Sheets**  
**December 31, 2006 and 2005**

	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation (Note 6)	\$ 23,688,751	\$ 17,951,634
Due from affiliate Novartis Pharmaceuticals Canada	1,116,767	
Finished goods inventory (net of reserves of \$13,225 and \$31,977 as of December 31, 2006 and 2005)	4,069,226	4,053,734
Other current assets	572,733	307,475
Total current assets	29,447,477	22,312,843
Long-term assets		
Insurance receivable (Note 7)	7,299,241	3,510,868
Intangible assets (Note 3) (net of amortization of \$35,531,923 and \$29,352,458 as of December 31, 2006 and 2005)	26,262,722	32,442,187
Total long-term assets	33,561,963	35,953,055
Total assets	\$ 63,009,440	\$ 58,265,898
<b>Liabilities and Members Capital</b>		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc. (Note 6)	\$ 8,566,562	\$ 9,787,307
Accrued liabilities	376,877	554,342
Product liability reserve (Note 7)	9,629,241	4,944,815
Allowance for returns (Note 4)	7,937,905	6,167,605
Total current liabilities	26,510,585	21,454,069
Commitments and contingencies (Note 7)		
Members capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	3,640,946	3,953,920
Total members capital	36,498,855	36,811,829
Total liabilities and members capital	\$ 63,009,440	\$ 58,265,898

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, 2006, 2005 and 2004**

	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Net sales</b>			
Third parties	\$ 128,973,730	\$ 119,331,180	\$ 101,834,528
Novartis Pharmaceuticals Canada, Inc.	2,969,045	2,226,126	3,578,932
	131,942,775	121,557,306	105,413,460
<b>Cost of sales</b>			
Sales to third parties	15,886,720	15,148,711	14,882,911
Sales to Novartis Pharmaceuticals Canada, Inc.	1,237,620	923,604	1,489,292
Noven royalties	6,845,122	6,444,033	5,203,932
Amortization of license/marketing rights	6,179,465	6,179,465	6,179,465
	30,148,927	28,695,813	27,755,600
Gross profit	101,793,848	92,861,493	77,657,860
<b>Operating expenses</b>			
Sales and marketing expenses	32,928,299	31,657,682	31,364,085
Administrative expenses	3,494,020	3,377,400	3,359,684
Product liability expenses, net of insurance receivable	896,053	533,947	900,000
Income from operations	64,475,476	57,292,464	42,034,091
<b>Other income</b>			
Interest income	841,564	461,294	191,287
Net income	\$ 65,317,040	\$ 57,753,758	\$ 42,225,378

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, 2006, 2005 and 2004**

	<b>Total</b>
<b>Members' capital at January 1, 2004</b>	\$ 48,199,843
Net income	42,225,378
Distributions to Novartis	(28,363,294)
Distributions to Noven	(19,775,736)
<b>Members' capital at December 31, 2004</b>	42,286,191
Net income	57,753,758
Distributions to Novartis	(35,583,169)
Distributions to Noven	(27,644,951)
<b>Members' capital at December 31, 2005</b>	36,811,829
Net income	65,317,040
Distributions to Novartis	(37,050,205)
Distributions to Noven	(28,579,809)
<b>Members' capital at December 31, 2006</b>	\$ 36,498,855

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, 2006, 2005 and 2004**

	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Cash flows from operating activities</b>			
Net income	\$ 65,317,040	\$ 57,753,758	\$ 42,225,378
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	(18,752)	31,977	
Changes in assets and liabilities			
(Increase) decrease in due from affiliate Novartis Pharmaceuticals Corporation	(5,737,117)	5,179,494	(1,798,501)
(Increase) decrease in due from affiliate Novartis Pharmaceuticals Canada, Inc.	(1,116,767)		696,620
Decrease (increase) in finished goods inventory	3,260	(1,908,275)	504,677
Increase in other current assets	(265,258)	(16,976)	(24,978)
Increase in insurance receivable	(3,788,373)	(2,810,868)	(700,000)
(Decrease) increase in due to affiliate Noven Pharmaceuticals, Inc.	(1,220,745)	(895,425)	3,518,108
(Decrease) increase in accrued liabilities	(177,465)	(628,594)	1,009,686
Increase in product liability reserve	4,684,426	3,344,815	1,600,000
(Decrease) increase in allowance for returns	1,770,300	(3,001,251)	(5,071,425)
Net cash provided by operating activities	65,630,014	63,228,120	48,139,030
<b>Cash flows from financing activities</b>			
Distributions to members (Note 5)	(65,630,014)	(63,228,120)	(48,139,030)
Net cash used in financing activities	(65,630,014)	(63,228,120)	(48,139,030)
Net change in cash			
<b>Cash and cash equivalents</b>			
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, 2006**

**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.

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).

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 (Notes 5 and 6).

**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**

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

**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements  
December 31, 2006**

during the reporting period. The most significant assumptions are employed in estimates used in the deductions from gross sales for allowances, rebates, 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, 2006, 2005, and 2004 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 reductions of revenue.

**Sales Allowances**

Novartis records the Company's sales net of sales allowances for chargebacks, Medicare Part D rebates, 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.

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:

**Table of Contents**

**Vivelle Ventures LLC**  
**d/b/a Novogyne Pharmaceuticals**  
**Notes to Financial Statements**  
**December 31, 2006**

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Gross sales	\$ 151,931,653	\$ 134,675,279	\$ 121,212,227
Sales returns	\$ 5,732,390	\$ 935,912	\$ 6,224,072
Managed health care rebates	10,117,301	8,018,050	7,898,343
Cash discounts	3,041,805	2,690,058	2,425,331
Medicaid and Medicare Part D rebates including prescription drug savings cards	980,498	938,423	1,340,483
Chargebacks	1,032,093	969,492	860,412
Other discounts	2,053,836	1,792,164	629,058
Total sales allowances	22,957,923	15,344,099	19,377,699
Net sales to third parties	\$ 128,973,730	\$ 119,331,180	\$ 101,834,528

**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 \$126,128, \$146,322, and \$118,936 for 2006, 2005, and 2004, 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, 2006**

Product liability claims which cover years in which the products were sold by the Company and years in which the products were sold by Novartis have been allocated between the Company and Novartis based on the ownership of the product during the period in which the injury is alleged to have occurred.

**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 certain assets 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. The Company also incurred and capitalized \$271,912 of legal services related to the acquisition.

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 \$35,531,923 and \$29,352,458 as of December 31, 2006 and 2005. Amortization expense is \$6,179,465 per year and is included in Cost of Sales.

The HT studies (Note 7) led to a triggering event in 2002 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 was no impairment.

Based on continued declining sales and the fact that further adverse changes in the market for hormone therapy products could have a material adverse impact on the ability of the Company to recover its investment, the Company continues to complete an annual impairment test of the intangible asset using projected undiscounted net cash flows applicable to CombiPatch®. Based on this test, the Company determined that there was no impairment as of December 31, 2006 and 2005. 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 and Product Recalls**

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.

The activity for the allowances for returns, including product recalls, for the years ended December 31, 2006, 2005 and 2004 is as follows:

**Table of Contents**

**Vivelle Ventures LLC**  
**d/b/a Novogyne Pharmaceuticals**  
**Notes to Financial Statements**  
**December 31, 2006**

<b>Balance January 1, 2004</b>	\$ 14,240,281
Current year provision	4,997,001
Prior year adjustment	1,227,071
Deduction returns processed	(11,295,497)
<b>Balance December 31, 2004</b>	<b>9,168,856</b>
Current year provision	3,320,440
Prior year adjustment	(2,384,528)
Deduction returns processed	(3,937,163)
<b>Balance December 31, 2005</b>	<b>6,167,605</b>
Current year provision	4,342,016
Prior year adjustment	1,390,374
Deduction returns processed	(3,962,090)
<b>Balance December 31, 2006</b>	<b>\$ 7,937,905</b>

**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. In 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 sales 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, 2006, 2005 and 2004.

**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements  
December 31, 2006**

affects more product than Noven's current testing and analysis suggests, additional recalls may be required, which could have a material and adverse effect on the Company's results of operations and prospects.

**5. Operating Agreement**

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

**Management Committee**

The Operating Agreement, as amended, provides for the formation of a Management Committee. The Members act on any matters to be determined by them through their representatives on the Management Committee. The Management Committee has general management powers with respect to the management and operation of the business and affairs of the Company and is responsible for policy setting and approval of the overall direction of the Company. The Management Committee consists of five individuals of whom three are designated by Novartis and two by Noven. A decision by the Management Committee is made by the affirmative vote of a majority of the Committee members. The Operating Agreement, as amended, also provides for certain actions or decisions to require the vote of at least four of the five members of the Management Committee. Those actions or decisions include but are not limited to approval of material amendments to the annual operating and capital budget for activities outside normal business, amendments to the documents concerning the formation of the Company, incurrence of indebtedness in excess of \$1 million, admitting a new member, acquiring or disposing of assets with a value in excess of \$500,000 or settlement of litigation in excess of \$1 million. The Members have further agreed that the approval of both Members is required to adopt or materially amend the annual sales and marketing plan or to enter into any contract with a third party sales force.

**Allocation of Net Income and Loss**

Net income is allocated at the end of each fiscal year in accordance with the accounting method followed by the Company for federal income tax purposes in the following order of priority:

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

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

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.

**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements  
December 31, 2006**

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 2006 distributions to Novartis and Noven of \$37,050,205 and \$28,579,809, respectively, are payments related to New Jersey state taxes of \$2,970,908 and \$2,212,070, respectively. 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.

**Buy/Sell and Dissolution Provisions**

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

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



**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements  
December 31, 2006**

**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, 2006, 2005 and 2004, Novartis charged the Company \$3,555,410, \$3,133,136 and \$2,796,760, respectively, for these services.

**Bookkeeping, Accounting and Treasury**

The books and records of the Company are maintained by Novartis. The Company's transactions are initially recorded in Novartis' general ledger and are transferred to the Company's ledger on a monthly basis with the corresponding entry being recorded as an amount Due to or from affiliate Novartis Pharmaceuticals Corporation. The balances in this account of \$23,688,751 and \$17,951,634, as of December 31, 2006 and 2005, 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, 2006, 2005 and 2004 at an average annual rate of 5.25%, 3.6% and 1.4%, respectively. During these periods, interest of \$841,564, \$461,294 and \$191,287, respectively, was earned and is reflected in the amount Due from affiliate Novartis Pharmaceuticals Corporation.

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

**Table of Contents**

**Vivelle Ventures LLC**  
**d/b/a Novogyne Pharmaceuticals**  
**Notes to Financial Statements**  
**December 31, 2006**

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 Pharmaceuticals Canada.

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

	<b>Years Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
Balance at the beginning of the period	\$ 17,951,634	\$ 23,131,128
Net sales - third parties (excluding returns)	134,706,120	120,267,092
Sales returns processed	(3,962,090)	(3,937,163)
Interest income on cash balances	841,564	461,294
Distributions to members	(65,630,014)	(63,228,120)
Payment to Noven for marketing services, inventory purchases and royalties	(56,699,396)	(55,134,309)
Disbursements made on behalf of the Company	(1,815,935)	(2,752,411)
Novartis service charges	(3,555,410)	(3,133,136)
Cash received from Novartis Canada	1,852,278	2,226,126
Other		51,133
<b>Total</b>	<b>\$ 23,688,751</b>	<b>\$ 17,951,634</b>

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.

During the years ended December 31, 2006, 2005 and 2004, Noven charged the Company \$20,926,359, \$20,768,126, and \$20,014,190, 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, 2006, 2005 and 2004 were \$10,551,108, \$8,970,238, and \$10,663,298, respectively.

**Table of Contents**

**Vivelle Ventures LLC**  
**d/b/a Novogyne Pharmaceuticals**  
**Notes to Financial Statements**  
**December 31, 2006**

These costs for field sales force staffing and marketing and advertising and other services in connection with the marketing and promotion of the products are included in the sales and marketing expenses line on the statement of operations.

**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 \$6,845,122, \$6,444,033 and \$5,203,932 for the years ended December 31, 2006, 2005 and 2004, respectively.

**Inventory Purchases**

Vivelle®, Vivelle-Dot® and CombiPatch® are manufactured by Noven and sold to the Company at an agreed upon price. Noven has ceased manufacturing of Vivelle for the Company at the end of 2006. During the years ended December 31, 2006, 2005 and 2004, the Company purchased products from Noven in the amounts of \$17,012,690, \$17,787,186 and \$15,216,288, 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-Novon Pharmaceuticals, Inc.**

The following represents the amounts payable to Noven related to:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Purchases of inventory	\$ 3,795,409	\$ 4,125,516
Services provided by Noven	3,056,883	3,835,010
Royalties	1,714,270	1,826,781
	<b>\$ 8,566,562</b>	<b>\$ 9,787,307</b>

**7. Commitments and Contingencies****Litigation, Claims and Assessments**

As of December 31, 2006, there have been 42 lawsuits that include 56 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 42 lawsuits filed, 5 lawsuits have been dismissed and 1 lawsuit has been settled for a nominal amount. For the remaining 36 pending lawsuits, 4 of these pending lawsuits name the Company, Noven and Novartis. Another of these pending lawsuits names Noven and Novartis, but not the Company, and another only names the Company. The remainder of the 36 lawsuits only name Novartis.

**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements  
December 31, 2006**

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

Although it is not possible to predict the ultimate outcome of its litigation or the indemnification provisions at this time, the Company established reserves in the amount of \$9,629,241 and \$4,944,815 as of December 31, 2006 and 2005, respectively, for expected defense and settlement expenses 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 \$7,299,241 and \$3,510,868 as of December 31, 2006 and 2005, respectively. Currently, although the Company's insurance carrier has sent the Company a reservation of rights letter, the coverage is not in dispute.

The Company plans to pursue having these claims treated as a serial loss. As of December 31, 2006, the Company's insurance carrier has not determined these claims to be a serial loss. Therefore, the Company has recorded a reserve for the deductible amount for each reported and incurred but not reported claim.

Additionally, with respect to CombiPatch® claims only, the Company purchased the right to that product pursuant to an asset purchase agreement (Note 3) which provides that the seller retains all product liabilities associated with the use, sale or disposal of CombiPatch® products on or before March 30, 2001, and the Company will seek to enforce this provision in cases to which it applies. At present no receivable has been recorded for this provision as the portion of the liability that can be attributed to the seller cannot be determined.

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 and, there is a risk that additional claims may be filed against the Company. 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.

**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements**

**December 31, 2006**

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 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.

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 Agreement**

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.

**Table of Contents**

**Vivelle Ventures LLC  
d/b/a Novogyne Pharmaceuticals  
Notes to Financial Statements  
December 31, 2006**

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 42 to 58 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.

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 38%, 37% and 20% in 2006, 35%, 37% and 21% in 2005, and 40%, 24% and 20% in 2004.