NOVEN PHARMACEUTICALS INC
Form 10-K
April 01, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2007

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to_____

Commission file number 0-17254
NOVEN PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**59-2767632**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11960 S.W. 144th Street, Miami, Florida	**33186**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code 305-253-5099
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $.0001	**NASDAQ Global Select 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 o No þ
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant was approximately $577 million (computed by reference to the price at which the common equity was last sold on June 29, 2007, the last business day of the registrant s most recently completed second fiscal quarter).

As of March 24, 2008, there were 24,560,432 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of the registrant s Proxy Statement for its 2008 Annual Meeting of Stockholders

NOVEN PHARMACEUTICALS, INC.
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Trademark Information: DOT Matrix® and DentiPatch® are registered trademarks of Noven Pharmaceuticals, Inc.; Lithobid® and Pexeva® are registered trademarks, and Mesafem and Stavzor are trademarks of Noven Therapeutics, LLC; Vivelle® is a registered trademark of Novartis Pharmaceuticals Corporation; Estradot® (foreign) and

Vivelle-Dot® are registered trademarks, and Menorest is a trademark, of Novartis AG; CombiPatch® and Estalis® (United States) are registered trademarks of Vivelle Ventures LLC; Femiest® is a registered trademark of Sanofi-aventis in Japan; 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; Duragesic® is a registered trademark of Johnson & Johnson Corporation; Ortho Evra® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.; Pristiq is a trademark of Wyeth Laboratories or affiliates; and Vyvanse is a trademark of Shire LLC.

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FORWARD-LOOKING INFORMATION

Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. These statements are made to enable a better understanding of our business, but because these 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 factors set forth under Risk Factors beginning on page 26 of this report.

PART I

Item 1. Business.

General Business & Strategy

Noven Pharmaceuticals, Inc. (we or Noven) is a specialty pharmaceutical company engaged in the research, development, manufacture, marketing and sale of prescription pharmaceutical products.

Our primary commercialized products include prescription transdermal patches utilizing our proprietary transdermal drug delivery technology for use in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and in menopausal hormone therapy (HT), as well as oral prescription products for use in the treatment of certain psychiatric conditions. Our developmental pipeline includes products in the women s health and central nervous system (CNS) categories.

Our business is focused in three principal areas:

Noven Transdermals is our transdermal drug delivery unit. Noven Transdermals researches, develops and manufactures transdermal patches, generally for pharmaceutical industry partners pursuant to development, license or other agreements that facilitate the commercialization of new transdermal patches. Commercialized products that have emerged from the Noven Transdermals development pipeline include Vivelle-Dot® (estradiol transdermal system), the most prescribed transdermal estrogen product in the United States;

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CombiPatch® (estradiol/norethindrone acetate transdermal system), the first two-drug combination patch approved in the United States; and Daytrana (methylphenidate transdermal system), the first and only patch for the treatment of ADHD. Developmental products in the Noven Transdermals pipeline include an amphetamine patch for ADHD and other transdermal product opportunities.

Novogyne Pharmaceuticals (Novogyne) is our women s health joint venture with Novartis Pharmaceuticals Corporation (Novartis). Through Novogyne, we market and sell in the United States HT patches developed and manufactured by Noven. The Novogyne marketing and sales functions, which have been managed by Noven since the joint venture was founded in 1998, have advanced Vivelle-Dot® to its current leadership position in the transdermal estrogen category.

Noven Therapeutics, LLC (Noven Therapeutics) became a wholly-owned subsidiary of Noven through our August 2007 acquisition of JDS Pharmaceuticals, LLC (JDS), a privately-held specialty pharmaceutical company with a targeted sales force, psychiatry and CNS expertise, two marketed products, and a pipeline of products in development. The Noven Therapeutics sales force currently sells the psychiatry products Pexeva® (paroxetine mesylate) and Lithobid® (extended release lithium carbonate) in the United States, and is expected to launch Stavzor (delayed release valproic acid softgel) in the United States in the second half of 2008. Noven Therapeutics product development pipeline includes Mesafem, a non-hormonal therapy for the treatment of vasomotor symptoms associated with menopause, and other products.

Our long-term strategy for growth is focused on: (i) expanding and diversifying the transdermal product offerings of Noven Transdermals through new transdermal product development activities and new or expanded industry collaborations; (ii) maximizing the opportunities presented at our Novogyne joint venture by continuing effective promotion of Vivelle-Dot® and seeking to expand the range of products offered by the Novogyne sales force; and (iii) leveraging the sales and marketing infrastructure and industry expertise of Noven Therapeutics through new product development (including transdermal products that may be developed), product acquisitions, and possibly strategic collaborations all with the goal of establishing Noven as a leading specialty pharmaceutical company with significant growth.

We regularly review our corporate strategies to evaluate their suitability and effectiveness in light of evolving business, industry, market and other conditions. We cannot assure 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.

With the addition of Noven Therapeutics, Noven s business is now comprised of two reportable segments: (i) Noven Transdermals, which currently consists of research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products; and (ii) Noven Therapeutics, which currently consists of development, marketing, sales and distribution of pharmaceutical products. Prior to the acquisition on August 14, 2007, Noven had one reportable segment. In accordance with Statement of Financial Accounting Standards No. 131 (SFAS No. 131), Disclosures about Segments of an Enterprise and Related Information, information for earlier periods has been recast. See Note 15 Segment and Customer Data for Noven s segment financial reporting.

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

Noven Transdermals

Our Noven Transdermals unit is engaged in the research, development, manufacture and marketing of advanced transdermal patches utilizing our proprietary drug delivery technologies. Our principal commercialized transdermal products are prescription patches for use in the treatment of ADHD and in HT. These products include:

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

Vivelle-Dot®, 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.

CombiPatch®, the first combination estrogen/progestin transdermal patch approved by the FDA. This product is marketed under the brand name Estalis® outside the United States.

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 side effects.

Our most advanced patches utilize our patented DOT Matrix ® patch technology. DOT Matrix® is a highly efficient class of diffusion-based drug-in-adhesive patch technology that can often deliver more drug through a smaller patch area than competitive patches without using irritating skin permeation enhancers and without compromising adhesion. We believe that reduced patch size can have a beneficial effect on patient preference and provide a competitive advantage over patches that deliver similar compounds through a larger patch. DOT Matrix® technology may also permit us to develop patient-friendly patches in cases where, due to the nature of the compound 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 ® technology, such as Daytrana, Vivelle-Dot ® and CombiPatch®, 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.

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Novogyne Pharmaceuticals

Our HT products are marketed and sold in the United States through Novogyne, a joint venture that we formed with 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 profitability has been dependent on our equity in earnings of Novogyne, a non-cash item.

Novogyne markets our Vivelle-Dot® and CombiPatch® products in the United States. Novogyne s sales and marketing efforts have helped Vivelle-Dot® to become the most prescribed product in the transdermal estrogen therapy (ET) category, with a 53% share of monthly total prescriptions written in the United States as of December 31, 2007. In connection with a transition to our advanced Vivelle-Dot® product, we ceased manufacture of our first generation estrogen patch (which was marketed as Vivelle®, Menorest® and Femiest®) in late 2006.

Under the terms of the joint venture agreements, we manufacture and supply Novogyne with, and perform marketing, sales and promotional activities for, Vivelle-Dot® and CombiPatch®. We receive product revenues (with a manufacturing margin) on our sale of Vivelle-Dot® and CombiPatch® finished product to Novogyne, and receive royalties from Novogyne based on Novogyne s sales of Vivelle-Dot®. We are also reimbursed by Novogyne for costs incurred by us on behalf of Novogyne, including costs associated with the Noven employees who comprise the Novogyne sales force and other Noven personnel who provide services to Novogyne. For its part, Novartis distributes Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne, including contracting with the managed care sector and all regulatory, accounting and legal services.

Novogyne is managed by a committee (the Management Committee) of five members, three of whom are appointed by Novartis and two of whom are appointed by Noven. The President of Novogyne is Jeffrey F. Eisenberg, who also serves as Executive Vice President and Interim Chief Executive Officer of Noven. Pursuant to the joint venture agreements, certain significant actions require a supermajority vote of the Management 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 s assets. The Management Committee has the authority to distribute cash to Novartis and Noven based upon a contractual formula. In the years ended December 31, 2007, 2006 and 2005, Novogyne made cash distributions of $28.8 million, $26.4 million and $26.2 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 2007, 2006 and 2005, our equity in earnings of Novogyne, as reflected in our consolidated statements of operations, was $35.9 million, $28.6 million and $24.7 million, respectively, representing 48.6%, 48.4% and 47.7%, respectively, of Novogyne s income after Novartis preferred returns for each of those years.

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Novartis has the right to dissolve the joint venture in the event of a change in control of Noven if the entity which acquires control 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® 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 operating agreement of the joint venture company.

The operating agreement of the joint venture company 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 sell its entire interest in Novogyne to Novartis.

Noven Therapeutics

In August 2007, we acquired JDS, a specialty pharmaceutical company that was privately-held at the time. The total purchase price for this acquisition consisted of $125.0 million cash paid at closing, approximately $5.4 million of transaction costs consisting primarily of fees paid for financial advisory, legal, valuation and accounting due diligence services, and approximately $0.5 million in connection with non-competition agreements entered into with two former executives of JDS. We funded the acquisition from the sale of short-term investments and accounted for the acquisition using the purchase method of accounting. JDS became an indirect, wholly-owned subsidiary of Noven as a result of the acquisition. In January 2008, we changed the name of the entity to Noven Therapeutics, LLC.

Noven Therapeutics currently markets and sells two prescription products:

Pexeva®, a selective serotonin re-uptake inhibitor (SSRI) antidepressant indicated for major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder. This product is one of only two remaining patented brands without a generic equivalent in the United States SSRI market. Pexeva® is subject to a composition of matter patent that extends to 2017 and other patents extending to 2022.

Lithobid®, an extended release lithium product and the only branded lithium product sold in the United States. Lithobid® is indicated for the maintenance of bipolar disorder and the treatment of related manic episodes.

In December 2007, the FDA granted tentative approval for our Stavzor product. The tentative approval relates to the use of Stavzor in the treatment of manic episodes associated with bipolar disorder, monotherapy and adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Tentative approval generally means that the FDA has

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concluded that a drug product has met all required quality, safety and efficacy standards, but because of existing patents and/or exclusivity rights, it cannot yet be marketed in the United States. The New Drug Application (NDA) for Stavzor, which was submitted under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act by Banner Pharmacaps (the developer, licensor and manufacturer of the product) references Abbott Laboratories Depakote® product. Based on receipt of tentative approval, we expect to receive FDA final approval of Stavzor during 2008, although we cannot assure that FDA final approval will be granted in this timeframe, if at all. If approved for marketing, Stavzor will be a branded product and it will not be AB-rated to or generically substitutable for Depakote®, and neither Depakote® nor any Depakote® generics will be substitutable for Stavzor. The Noven Therapeutics sales force will promote the Stavzor brand.

In addition, Noven Therapeutics is advancing a pipeline of therapeutic products in development, including Mesafem, a women s health product for use in the treatment of vasomotor symptoms associated with menopause. Our business strategy includes leveraging Noven Therapeutics marketing and sales infrastructure with next-generation psychiatry products and complementary products that we seek to develop or acquire.

Products

The following table sets forth certain information regarding our commercialized products and products under development.

Product	Indication	Commercialized or Developmental	Regulatory Status
	Noven Transdermals		
Vivelle-Dot® /Estradot®	Menopausal Symptoms/ Osteoporosis	Commercialized	FDA-approved; Approved in multiple foreign countries
CombiPatch®/Estalis®	Menopausal Symptoms/ Osteoporosis	Commercialized	FDA-approved; Approved in multiple foreign countries
Daytrana	ADHD	Commercialized	FDA-approved; Application filed in European Union, Canada
Amphetamine Patch	ADHD	Developmental	Completed Phase 1 study
HSDD Patch	Hypoactive Sexual Desire Disorder	On Hold	Partner s NDA withdrawn in December 2004; United States development currently on hold.
	Noven Therapeutics		
Pexeva®	Major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder	Commercialized	FDA-approved
Lithobid®	Bipolar disorder and related manic episodes	Commercialized	FDA-approved

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Product	Indication	Commercialized or Developmental	Regulatory Status
Stavzor	Bipolar disorder, migraine therapy and epilepsy	Developmental	FDA tentative approval; United States launch expected in 2008
Stavzor ER	Bipolar disorder, migraine therapy and epilepsy	Developmental	Pre-clinical
Lithium QD	Bipolar disorder and related manic episodes	Developmental	Evaluating development program
Mesafem	Vasomotor symptoms (hot flashes)	Developmental	Phase 3 clinical trials planned in 2008
		Transmucosal	
DentiPatch®	Dental pain associated with certain dental procedures	Commercialized	FDA-approved

Commercialized Products

Hormone Therapy

Overview

Our menopausal HT products consist of:

Vivelle-Dot® /Estradot® our advanced transdermal estrogen patch; and

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

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

Vivelle-Dot®/Estradot®

Utilizing our proprietary DOT Matrix technology, our advanced transdermal estrogen patch (marketed as Vivelle-Dot® and Estradot®) is one-third the surface area of our previous Vivelle® estrogen patch at any given dosage level, yet provides the same delivery of drug over the same timeframe. This system is more flexible and comfortable to wear than the original product, with a lower potential for skin irritation. Vivelle-Dot® is the most prescribed transdermal ET product in the United States. This product is currently available in the United States in five dosage strengths. The lowest dosage strength is approved only for prevention of osteoporosis and, in light of the HT studies

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and labeling requirements discussed below, 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). Sanofi-aventis (Aventis) has marketing rights for Vivelle-Dot® in Japan. For all other countries, Novartis Pharma holds the rights to market this product under the name Estradot®, as well as any product improvements and future generations of estrogen patches developed by us.

Under the terms of our license to Novartis Pharma, Novartis Pharma is responsible for seeking approval to market Estradot® in its territories. The product has been approved for marketing in over 30 foreign countries and Novartis Pharma has launched the product in a number of European countries. There can be no assurance that commercialization of the product in these countries will be successful or that Novartis Pharma will successfully launch Estradot® in 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 a 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.

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® expired in January 2003. Since the expiration of this agreement, the parties have continued to operate in accordance with certain of the supply agreement s pricing terms. We cannot assure that we and Novogyne will continue to operate under the supply agreement in accordance with its pricing terms or 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 pricing terms could have a material adverse effect on our business, consolidated results of operations and financial condition. 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 and Novartis in a favorable manner.

CombiPatch® /Estalis ®

We developed the first combination transdermal HT system approved for marketing by the FDA (marketed as CombiPatch® and Estalis®), 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

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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.

The HT Product Market

We currently derive a significant portion of our revenues from our HT products. Our total HT-related revenues were $45.6 million, $42.7 million and $43.8 million for 2007, 2006 and 2005, respectively, which represented 55%, 70% and 83%, respectively, of our revenues in each of those years.

Since 2002, several studies, including the Women s Health Initiative (WHI) study performed by the National Institutes of Health (NIH) and a study performed by the National Cancer Institute (NCI), have identified increased risks from the use of HT, including increased risks of invasive breast cancer, ovarian cancer, stroke, heart attacks and blood clots. As a result of the findings from these 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 HT 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 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 HT products are not being used in the study, the market for our HT 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.

ADHD Therapy

Overview

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.

Daytrana

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

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symptoms of ADHD and is approved for children aged six to twelve years. The FDA approved Daytrana in April 2006. The product combines the active ingredient methylphenidate with our DOT Matrix technology and is designed to provide continuous release of medication throughout the day.

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. Among other advantages we believe Daytrana possesses as compared to certain oral ADHD medications, we believe that Daytrana provides physicians and parents with broad dosing flexibility because dosing can be controlled by removing the patch earlier than the end of the nine hour wear time.

Shire, the market leader in the ADHD therapeutic category, is the exclusive, global licensee of Daytrana pursuant to a license agreement established between Noven and Shire in 2003. Under the license agreement, we granted Shire the exclusive global rights to market Daytrana in exchange for payments by Shire of up to $150.0 million (payable in increments as set forth below) and ongoing manufacturing revenues. Pursuant to the terms and conditions of the license agreement, Shire made payments to us of $25.0 million upon the closing of the transaction in April 2003 and $50.0 million upon receipt of final marketing approval for Daytrana by the FDA in April 2006. The remaining $75.0 million was payable in three equal installments of $25.0 million 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. We received the first and second $25.0 million sales milestone payments in the first and third quarters of 2007, respectively. The third sales milestone has not yet been achieved. 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 each milestone is achieved through the first quarter of 2013.

Under the license agreement, Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of April 2008 or 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. Noven and Shire are also parties to a long-term supply agreement under which we manufacture and supply Daytrana to Shire at a fixed price. In 2007, our product sales of Daytrana to Shire were $13.4 million. The supply 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.

After the product launch in 2006, we received reports from some consumers concerning the difficulty of removing the release liner from Daytrana patches. In the first quarter of 2007, Noven and Shire implemented enhancements to the Daytrana release liner intended to improve ease of use of the patch. While the enhanced release liner has reduced the level of consumer reports, we continue to seek further enhancements to the Daytrana release liner to further improve the ease of use of the patch. The market share of Daytrana remained substantially unchanged during 2007.

In July 2007, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. The majority of these observations related to the

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Daytrana patch and difficulties experienced by some patients in removing the product s release liner, including certain product lots that utilize an enhanced release liner. In July 2007, we submitted to the FDA our response to the Form 483.

In the third quarter of 2007, Shire initiated voluntary market withdrawals of a portion of the Daytrana product on the market, primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana patches. In February 2008, we paid Shire $3.3 million related to the 2007 withdrawals. These amounts were charged to operations in the third quarter of 2007.

In January 2008, we received a warning letter from the FDA in connection with the FDA s mid-2007 inspection of our manufacturing facilities. In the letter, the FDA cites Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana s release liner; and (ii) data supporting the peel force characteristics of Daytrana s enhanced release liner throughout the product s shelf life. The warning letter, which is posted at the FDA s website at www.fda.gov, requested additional information and analysis related to the cited deficiencies and instructed us to take prompt action to address the FDA s concerns. We submitted our response to the warning letter on January 30, 2008. We cannot assure that our response will be acceptable to the FDA or satisfactorily address the FDA s concerns.

Our business will be significantly harmed if we are unable to adequately resolve the issues raised by the FDA in the January 2008 warning letter as well as the production and other issues involving Daytrana. For a detailed discussion of the risks and uncertainties facing Daytrana, please see the risk factor discussion beginning on page 26 of this Form 10-K.

Noven Therapeutics

Our commercialized therapeutic psychiatry products consist of Pexeva®, an SSRI antidepressant, and Lithobid®, an extended release lithium product. We market and sell Pexeva® and Lithobid® through the Psychiatry/CNS marketing and sales infrastructure of Noven Therapeutics that we obtained when we acquired JDS. These products are manufactured by third parties and supplied to us under manufacturing and supply agreements. Accordingly, we depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations, and our sales of these products and results of operations may be adversely impacted if they fail to do so.

Pexeva®

Pexeva® is an SSRI antidepressant indicated for major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder. This product is one of only two remaining patented brands without a generic equivalent in the United States SSRI market. Pexeva® is subject to a composition of matter patent that extends to 2017, as well as other patents that extend to 2022.

JDS acquired Pexeva® from Synthon Pharmaceuticals, Inc. (Synthon) in November 2005. In this transaction, JDS purchased certain assets related to Pexeva®, including the NDA, intellectual property (including patents and trademarks) and certain finished goods inventory. JDS purchase of Pexeva® included a cash payment at the time of closing and an obligation to make certain future fixed payments and certain contingent payments. Upon our acquisition of JDS, we became responsible to Synthon for up to $11.5 million in contingent payments under the asset purchase

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agreement. We accrued for these contingent payments at the time of closing of the JDS transaction, and related costs were allocated to intangible assets acquired.

Lithobid®

Lithobid®, an extended release lithium product, is the only branded lithium product sold in the United States. This product is indicated for the maintenance of bipolar disorder and the treatment of related manic episodes.

JDS acquired Lithobid® from Solvay Pharmaceuticals, Inc. (Solvay) in August 2004. In this transaction, JDS purchased certain assets related to Lithobid®, including the NDA, intellectual property (including trademarks) and certain finished goods inventory. JDS purchase of Lithobid® included a cash payment at the time of closing and a promissory note made by JDS in favor of Solvay, which was paid in full prior to the closing of our acquisition of JDS. In connection with JDS acquisition of Lithobid®, JDS entered into an agreement requiring Solvay to manufacture and supply Lithobid® for up to five years. Prior to our acquisition of JDS, Solvay assigned this agreement to ANI Pharmaceuticals, Inc. (ANI). In December 2007, Noven Therapeutics and ANI agreed to terminate the Solvay agreement and enter into a new manufacturing and supply agreement containing substantially similar terms and conditions as the prior 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 consolidated results of operations.

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Products Under Development

Research and Development

Our long-term prospects are dependent upon the successful development of new products and their successful commercialization. Our research and development program at Noven Transdermals investigates and seeks to identify compounds that can be delivered transdermally which we believe may have substantial market potential, as well as transdermal products that we believe can be improved by using our patented technologies. We typically seek to develop transdermal 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 transdermal technology may be beneficially applied. As part of our transdermal development 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. We have entered into several early stage feasibility and/or development agreements with other pharmaceutical companies to determine the feasibility of transdermal delivery of various compounds.

Our research and development program at Noven Therapeutics is described below under Noven Therapeutics Products Under Development.

For the years ended December 31, 2007, 2006 and 2005, our research and development expense was $14.0 million, $11.5 million and $13.2 million, respectively. To bring Noven Therapeutics pipeline of products under development to market, we plan to significantly increase our research and development expenses beginning in 2008. See Management s Discussion and Analysis of Financial Condition and Results of Operations Outlook.

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.

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.

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Transdermal Product Development Collaborations

Amphetamine Transdermal System

In addition to our agreements with Shire related to Daytrana, in June 2004 we entered into an agreement with Shire for the development of an amphetamine patch for ADHD. Amphetamine-based products represent a significant portion of the United States market for ADHD therapies. This agreement was amended in July 2006 and, 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 development rights to the product. We completed a Phase 1 clinical trial for the product in March 2007. In June 2007, Shire exercised its option to acquire the exclusive development rights to the product and paid us the $5.9 million option payment. This $5.9 million payment and the initial $1.0 million payment have been included in deferred license and contract revenues on our consolidated balance sheet as of December 31, 2007. Shire has requested modifications to the patch formulation in order to align the amphetamine patch with Shire s future direction in ADHD and has agreed to pay us for our development efforts in this regard.

Transdermal System for HSDD

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 United States, P&G Pharmaceuticals withdrew its NDA for Intrinsa in December 2004 based on, among other factors, safety concerns expressed by an FDA Advisory Committee. P&G Pharmaceuticals has indicated that work on Intrinsa for the United States 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 United States, or if their evaluation of alternatives significantly delays the project, our collaboration with P&G Pharmaceuticals will be adversely affected.

Noven Therapeutics Products Under Development

Stavzor and Stavzor ER

Pursuant to an agreement between Noven Therapeutics and Banner Pharmacaps (Banner), we hold marketing rights to Stavzor and Stavzor ER (valproic acid extended release). These products utilize a proprietary enteric-coated soft gelatin capsule delivery system and, if approved, are expected to be indicated for use in the treatment of bipolar disorder and epilepsy, as well as in migraine therapy. We anticipate that these products will compete with Abbott Laboratories Depakote® and Depakote® ER products. In December 2007, the NDA for Stavzor received tentative approval from the FDA. We expect to launch Stavzor through the Noven Therapeutics sales and marketing infrastructure in 2008. Stavzor ER is in pre-clinical development by Banner; however, we cannot assure that Stavzor ER will be successfully formulated, developed, approved or commercialized.

Under the April 2007 development, license and supply agreement between JDS and Banner, Banner granted JDS the marketing rights to Stavzor and Stavzor ER in exchange for a cash payment at closing and $6.0 million in contingent payments which are payable to Banner over the

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course of development of the products upon the achievement of specified development and sales milestones. As a result of our acquisition of JDS, we are responsible to Banner for these contingent payments. The agreement also provides that Banner shall be the exclusive supplier of the products licensed under the agreement.

Lithium QD

Lithium QD, a developmental once-daily form of lithium carbonate, is in clinical development. It is subject to United States patents that extend to 2022 and may benefit from three years of exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Currently, there is no once-daily lithium product on the market. We believe that a once-daily lithium product has the potential to improve patient compliance and reduce high serum level peaks common with products prescribed in multiple doses per day. In October 2007, a Phase 3 clinical trial of Lithium QD did not achieve its primary endpoint with statistical significance. The Lithium QD project is currently under analysis and continued development is under evaluation. If we proceed with development, additional clinical studies will be required to complete development of this product at substantial additional cost. We cannot assure that development will be completed or that the product will ultimately be approved.

In March 2004, JDS acquired certain United States and international patents and other intellectual property related to Lithium QD for the purpose of developing, obtaining regulatory approval, manufacturing and marketing the product in the United States, Canada and certain other countries. The asset purchase agreement provides for potential future payments to the seller of up to $4.0 million subject to the achievement of certain development milestones. JDS separately entered into an exclusive supply agreement for the manufacture of Lithium QD, which also provides for additional potential development milestone payments of up to $2.0 million. As a result of our acquisition of JDS, we will be responsible for these payments if the milestones are achieved.

Mesafem

As part of the JDS acquisition, we acquired a women s health product called Mesafem that, if approved, would complement our expertise in the women s health area. Mesafem is a low-dose paroxetine mesylate capsule under development for the treatment of vasomotor symptoms associated with menopause, including hot flashes and night sweats (VMS). Published clinical data has demonstrated the efficacy of paroxetine for this indication. Mesafem is subject to the same patents as Pexeva®, as well as other pending patent applications and may benefit from three years of exclusivity under the Hatch-Waxman Act. We expect but cannot assure that Mesafem will enter Phase 3 clinical trials in 2008, with an NDA filing possible in 2009.

If successfully developed and approved, Mesafem would provide women with an alternative to HT products for VMS. It would participate in a new market segment that is expected to include Pristiq, a Wyeth product under development for VMS. Over 20 million women in the United States are affected by VMS and, of that number, only about 5 million are under treatment for the condition.

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Competition

General

The markets for our products are highly competitive. Competition in the pharmaceutical industry is generally based on a company s marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. Acceptance by physicians and other health care providers, including managed care groups, is also critical to the success of a product. The first product on the market in a particular pharmaceutical 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 or cause them to fall out of favor with physicians. 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.

Competition Relating to Our Transdermal Products

All transdermal 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 transdermal products being marketed or developed by us face, or will face, competition from other transdermal products that deliver the same or alternative drugs to treat the same indications.

As a general matter, transdermal drug delivery systems are more expensive and difficult to manufacture than oral formulations. 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, Vivelle-Dot® or our other products could, prior to the expiration of the applicable patent periods, face competition from a generic product if approved through the ANDA process or from a functionally-equivalent product that avoids infringing our patents.

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, Allergan, 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

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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.

Competition Facing Noven Therapeutics

Pexeva® participates in the highly competitive United States SSRI market. In this market, we compete against, among others, Lilly, GlaxoSmithKline plc (GlaxoSmithKline) and Pfizer Inc. (Pfizer). In addition, although Pexeva® is one of only two remaining patented brands without a generic equivalent in the United States SSRI market, it competes with generic versions of similar products with identical therapeutic profiles. We also compete in the United States SSRI market against manufacturers of emerging antidepressants, such as norepinephrine reuptake inhibitors, substance P antagonists and CRF receptor antagonists.

In the market for the treatment of bipolar disorder and related manic episodes, Lithobid® competes against, among others, an AB-rated generic equivalent product, products marketed by Lilly, GlaxoSmithKline and AstraZeneca PLC (AstraZeneca), as well as generic versions of other lithium products and antiepileptic and antipsychotic agents.

Many of our competitors in these markets, including Lilly, GlaxoSmithKline, AstraZeneca and Pfizer, are substantially larger and have greater financial resources than Noven. Additionally, manufacturers of generic products typically do not bear significant research and development or education and marketing development costs and, consequently, may be able to offer their products at considerably lower prices than we are able to offer our products.

Dependence on Licensees and the Novogyne Joint Venture

During 2007, 36%, 33%, and 18% of our revenues were attributable to Novogyne, Shire and Novartis Pharma (and its affiliates), respectively, and our profitability has been dependent on our equity in Novogyne s earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novogyne, Novartis Pharma, 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 transdermal products would cause the quantity of such products purchased from us and the amount of manufacturing revenues, 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® and CombiPatch® in the United States through our participation in the management of Novogyne, but the Management Committee of Novogyne is comprised of a majority of Novartis representatives, and we will not be able to control those matters. Our agreements with Shire require Shire to use reasonable commercial efforts to market Daytrana until the earlier of April 2008 or payment of all sales 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 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.

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Manufacturing

We internally manufacture our transdermal products. Our headquarters and transdermal manufacturing facility are 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. 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 transdermal products.

As discussed above under ADHD Therapy Daytrana , we received a warning letter from the FDA in January 2008 in connection with a mid-2007 FDA inspection of our manufacturing facilities. In the letter, the FDA cites Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of the release liner used in the Daytrana patch; and (ii) data supporting the peel force characteristics of the products s enhanced release liner throughout the product s shelf life. The warning letter, which is posted on the FDA s website at www.fda.gov, requested additional information and analysis related to the cited deficiencies and instructed us to take prompt action to address the FDA s concerns. We submitted our response to the warning letter on January 30, 2008. We cannot assure that our response will be acceptable to the FDA or satisfactorily address the FDA s concerns.

Some raw materials essential to our transdermal business are readily available from multiple sources. Certain raw materials and components used in the manufacture of our transdermal products (including essential polymer adhesives and other critical components) are, however, available from limited sources, and in some cases, a single source. In addition, the DEA controls access to controlled substances (including methylphenidate 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 transdermal 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 transdermal 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.

Pursuant to manufacture and supply agreements, we rely upon third party manufacturers to manufacture and supply us with Pexeva®, Lithobid® and, upon FDA approval, Stavzor. We depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations and their agreements with us. Additionally, we have no control over whether third party manufacturers breach their agreements with us or whether they determine to terminate or decline to renew agreements with us. Certain third party agreements prevent us from qualifying a second source of supply. Even where we are permitted to qualify a second source of supply, we expect it will be difficult and potentially costly and time-consuming for us to qualify a second source of product supply if necessary. Any interruption in our ability to obtain product supply and sell our products could adversely affect our present and future sales margins, market share and product pipeline, as well as harm our overall business.

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Marketing and Sales

We maintain two sales forces a psychiatry/CNS sales force in support of Noven Therapeutics products, and a women s health sales force that we manage on behalf of our Novogyne joint venture. In general, we rely on industry partners to market and sell products developed by Noven Transdermals, although we may retain rights to certain of those products for marketing and sale by Noven.

At Noven Therapeutics, we maintain a targeted specialty sales force and related sales and marketing infrastructure in support of our Pexeva® and Lithobid® products. This sales force will also promote our Stavzor® product, which we expect to launch in the second half of 2008. We acquired this sales force as part of our acquisition of JDS in August 2007. The Noven Therapeutics sales force is currently comprised of approximately 50 sales representatives.

On behalf of our Novogyne joint venture, we maintain and manage an approximate 120-person women s health sales force and related sales and marketing infrastructure in support of our Vivelle-Dot® and CombiPatch® products, which products are sold in the United States through Novogyne. In general, Noven s costs associated with these employees and substantially all of Novogyne s sales and marketing activities are reimbursed by Novogyne. Accordingly, these costs do not appear as expenses on Noven s consolidated statements of operations. 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. We believe the expertise we have established in women s health through Novogyne may benefit the commercialization of Noven Therapeutics Mesafem product for menopausal vasomotor symptoms, if approved and marketed.

At Noven Transdermals, our strategy has historically been to retain manufacturing rights and to rely on collaborative partners with the marketing and sales resources necessary to broadly commercialize the products under development. This reflects the fact that products in development at Noven Transdermals are generally not focused in a single therapeutic category and therefore cannot be effectively addressed by a single sales force. Our growth strategy includes the possibility that we may retain all rights to a new transdermal product, and develop, market and sell it ourselves, particularly if it is aligned with the therapeutic focus of Noven Therapeutics. Such a decision could result in substantial research, development, sales, marketing and other expenses that could adversely affect our results of operations over a period of years.

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 325 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 135 pending patent applications worldwide. In addition, in conjunction with the JDS acquisition, we have obtained four United States patents directed to paroxetine mesylate and lithium products in the United States, approximately 21 foreign patents and approximately 13 applications pending 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,

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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 beginning on the effective filing date.

We are unaware of any challenge to the validity of our patents that could have a material adverse effect on our business or prospects. Other than the allegations made by Johnson-Matthey in the matter discussed below under Item 3 Legal Proceedings, we are unaware of any third party claim of patent infringement with respect to any of our products that could have a material adverse effect on our business and 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, nor 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. Specifically, Pexeva® and Mesafem are subject to a composition of matter patent that extends to 2017. However, recent Supreme Court case law (unrelated to our patent) may make it easier to challenge the validity of this patent on grounds of obviousness. 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.

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

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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 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 the FDA s ANDA regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on any approved product s patent listed with the FDA or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product s patent or that such patent is invalid, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent. Under the Hatch-Waxman Act, the FDA may not finally approve the ANDA until the earlier of 30 months after 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. We cannot assure, even if we are otherwise entitled to such exclusivity, that such exclusivity 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

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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 1 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 2 trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase 1 trials, generally at differing dosages. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at a number of separate clinical test sites. Phase 4 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 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

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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 and amphetamine. We produce transdermal drug delivery products, and our third party manufacturers produce Pexeva® and Lithobid®, 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 or any of our third party manufacturer s approved manufacturing facilities becomes inoperable, obtaining the required FDA approval to manufacture the applicable product 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. As discussed above under ADHD Therapy Daytrana, we received a warning letter from the FDA in January 2008 in connection with the FDA s July 2007 inspection of our manufacturing facilities.

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

Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, sales practices, laboratory and manufacturing practices, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state, 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 future capital expenditures and has not had, and is not presently expected to have, a material adverse effect on our earnings or competitive position.

In addition, in recent years, several states and localities, including California, the District of Columbia, Maine, Massachusetts, Michigan, Minnesota, New Mexico, Ohio, Rhode Island, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failing to comply with these regulations are unclear. Furthermore, individual states, acting through their attorneys general, have become active, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. As a result of our acquisition of JDS, we market and sell our therapeutic products through our own sales force. We have recently implemented a compliance program designed to monitor and assist us in our compliance with these rules and regulations. Unless we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

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Backlog

Our backlog totaled $2,914,917 as of March 7, 2008, substantially all of which is expected to be filled during 2008. Our backlog totaled $1,097,144 as of March 1, 2007, all of which was filled during 2007.

Employees

As of December 31, 2007, we had approximately 586 employees, approximately 255 of which were engaged in manufacturing, process development, quality assurance and quality control, 219 in marketing and sales, 72 in general administration, 28 in research and development and 12 in clinical research and regulatory affairs. Included in these numbers are 74 individuals who became employees of Noven as a result of our acquisition of JDS in August 2007. Also included are approximately 157 employees whose salaries are reimbursed, in whole or in part, by our Novogyne joint venture. No employee is represented by a union and we have never experienced a labor-related work stoppage. We believe our employee relations are good.

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.

Available Information

Our Internet website address is www.noven.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports are available free of charge through our website, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the 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 our 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.

This 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 necessarily listed in order of priority and are not the only ones we face. If any of the following risks actually occurs, our business, financial condition and results of operations would suffer. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations.

Our business may be significantly harmed if we are unable to adequately resolve the issues raised by the FDA in the warning letter we received in January 2008.

In January 2008, we received a warning letter from the FDA in connection with the FDA s July 2007 inspection of our manufacturing facilities in Miami, Florida. An FDA warning letter is intended to provide notice to a company of violations of the laws administered by the FDA and to elicit voluntary corrective action.

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In the warning letter, the FDA cites Current Good Manufacturing Practice deficiencies related to our Daytrana patch and the: (i) peel force specifications for removal of Daytrana s release liner; and (ii) data supporting the peel force characteristics of Daytrana s enhanced release liner throughout the product s shelf life. The warning letter, which is posted at the FDA s website at www.fda.gov, requested additional information and analysis related to the cited deficiencies and instructed us to take prompt action to address the FDA s concerns. We submitted our response to the warning letter on January 30, 2008. We cannot assure that our response will be acceptable to the FDA or satisfactorily address the FDA s concerns.

Unless the violations identified in the warning letter are corrected, the FDA may withhold approval of marketing applications relating to products manufactured at our Miami, Florida facility. Failure to take effective corrective actions can result in FDA enforcement action such as monetary fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any enforcement action by the FDA would have a material adverse effect on us, including the potential loss of Daytrana sales, potential loss of sales of other products, the potential inability to achieve the remaining Daytrana sales milestone, the potential for litigation related to this matter, harm to our reputation and various costs associated with the foregoing.

Recalls or withdrawals of our products could have a material adverse effect on our results of operations and financial condition.

Product recalls or withdrawals 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 Vivelle-Dot®, CombiPatch® and Daytrana products), the FDA, other government agencies, or a combination of these parties. Our products may be recalled or we or our partners may withdraw products from the market for various reasons including the failure of our products to maintain their stability through their expiration dates, manufacturing issues, quality claims, safety issues or disputed labeling claims. As a general matter, the manufacture of transdermal delivery systems is more complex than for oral products, which may increase the risk of a recall or market withdrawal of one or more of our transdermal products.

We have experienced a number of production issues, some of which have led to recalls and market withdrawals in the past. In the third quarter of 2007, Shire initiated voluntary market withdrawals of a portion of the Daytrana product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana patches. In addition to our costs directly relating to the withdrawal, we paid Shire $3.3 million in February 2008 for its costs related to the withdrawals. Such costs were charged to operations in the third quarter of 2007. By reducing Shire s sales of Daytrana in 2007, the market withdrawals could delay the timing and ultimately affect our ability to achieve the third and final Daytrana sales milestone, which is based on Shire s net sales of the product exceeding $75 million calculated on a trailing 12-month basis.

We cannot assure that there will not be further recalls or market withdrawals of our products in the future. We do not carry any insurance to cover the risk of a potential product recall or market withdrawal. A significant product recall or market withdrawal 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.

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

Our success depends on the market acceptance of our products. Substantially all of our revenues have historically been generated through sales of transdermal delivery systems, which generally are more expensive than oral formulations. Our transdermal 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 other 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 transdermal products.

The market for Daytrana may be negatively affected by the FDA warning letter, the 2007 voluntary market withdrawals and other factors. In the first quarter of 2007, we, together with Shire, implemented enhancements to the Daytrana release liner intended to improve ease of use of the patch. Our results of operations and financial condition could be adversely affected if the enhancements do not result in improved ease of use of the Daytrana product throughout its shelf life. The market share of Daytrana remained substantially unchanged during 2007.

If we cannot develop, license or acquire new products and commercialize them on a timely basis, our financial condition 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. We cannot assure 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. We cannot assure that we will have the financial resources necessary to complete products under development, that those projects to which we dedicate resources will be successfully completed, that we will be able to obtain regulatory approval for any such product, or that any approved product 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 that may cause a product in development to fail or be delayed are beyond our control, including but not limited to:

- difficulty in enrolling patients in clinical trials;
- 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.

Furthermore, the potential success of a new pharmaceutical product is subject to many risks, including, but not limited to:

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the failure of ongoing and planned clinical trials and the risk that results from early-stage clinical trials may not be indicative of results in later-stage trials;

the unproven safety and efficacy of products under development;

the difficulty of predicting FDA approval, including the timing of approval and that approval may not be granted at all;

while FDA approval may be granted, the possibility that any expected period of exclusivity may not be realized and that we may not be able to produce commercially viable quantities;

the difficulty of predicting acceptance and demand for new pharmaceutical products;

the impact of competitive products, pricing and managed care and formulary status;

the possibility that any product launch may be delayed or that product acceptance may be less than anticipated;

the possibility that patent applications may not result in issued patents and that issued patents may not be enforceable or could be invalidated;

the commercial markets that we intend to enter with new products may not develop in the manner or to the extent that we anticipate; and

the potential negative impact of competitive responses to our sales, marketing and strategic efforts.

Any of the above factors may have a material adverse effect on our business, financial condition and results of operations.

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. We cannot assure 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. We cannot assure 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.

In order to diversify and complement our current product offerings, we may pursue new product and technology acquisitions. Any such acquisition will cause us to incur a variety of costs, and we cannot assure that we will realize the anticipated benefits of the acquisition.

One of our current growth strategies is to diversify our transdermal product offerings (beyond ADHD and HT) and complement our therapeutic product offerings through, among other things, new product acquisitions or the license or purchase of rights to new technologies. If we undertake any such product or technology acquisition, the process of integrating the new product or technology may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. We may fail to realize the anticipated benefits of any such acquisition for a variety of reasons, including as a result of an acquired technology proving to not be safe or effective in later clinical trials or the technology being found to infringe upon the intellectual property rights of another. We may fund any future acquisition through debt financing or the issuance of 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. Such funds may not be available on terms that are favorable to us, or at all. In particular, the credit markets are currently highly volatile, which could affect our ability to

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debt financing. 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.

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 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 when expected, or at all, 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.

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.

We may not realize the expected benefits of the Noven Therapeutics acquisition.

We may be unable to take advantage of the opportunities that we expect to obtain from the Noven Therapeutics acquisition. We cannot be certain of the future success of the currently marketed therapeutic products or, more importantly, the pipeline of therapeutic products under development that we acquired in the Noven Therapeutics acquisition. The potential success of any new pharmaceutical product is subject to a number of risks and uncertainties, including, among others, the risks and uncertainties described in the previous risk factor. As discussed in further detail under Item 1 Business Products Under Development above, a Phase 3 clinical trial of Lithium QD did not achieve its primary endpoint with statistical significance and continued development of this product is under evaluation.

We may not successfully integrate Noven Therapeutics into our existing business or such integration may be more costly or more difficult than expected.

The Noven Therapeutics acquisition involves the integration of companies that have previously operated independently, which is a complex, costly and time-consuming process. In addition, this is the first time that we have undertaken an acquisition of this size. The difficulties of combining the companies operations include, among other things:

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retaining key customer and vendor relationships;

the necessity of coordinating geographically disparate organizations, systems and facilities;

consolidating corporate and administrative functions and eliminating redundancies;

limiting the diversion of management resources necessary to facilitate the integration;

implementing compatible information and communication systems, as well as common operating procedures;

creating compatible financial controls and comparable human resource management practices;

expenses of any undisclosed or potential legal liabilities;

preserving, and preventing disruption of, the important contractual and other relationships of each company; and

assimilating and retaining employees with diverse business backgrounds.

The successful integration of Noven Therapeutics business has required us to take on new functions (such as commercial distribution and managed care) with which we do not have significant experience. Consistent with Noven Therapeutics practice prior to the acquisition, we intend to outsource many of these functions to third parties. We cannot assure that we will be successful in our efforts to develop or oversee these new capabilities in our business.

The process of integrating operations could cause an interruption of the activities of our business (including the operations of Noven Therapeutics business) and the loss of key personnel. The diversion of management s attention, any delays or difficulties encountered in connection with the business combination and the integration of the companies operations or the costs associated with these activities could have a material adverse effect on our business, financial condition and results of operations. We cannot assure that we can successfully integrate Noven Therapeutics business with our operations, that we will otherwise succeed in operating Noven Therapeutics business and continue the development of its products or that the financial results of the combined companies will meet or exceed the financial results that we would have achieved without the acquisition.

The Noven Therapeutics acquisition is expected to dilute our earnings for an undetermined period of time.

Our financial results reflect significant amortization and other ongoing integration-related expenses associated with our acquisition of Noven Therapeutics. In addition, we anticipate significantly increasing our research and development expenses for an extended period of time as we continue development of the therapeutic products under development acquired in the acquisition. We cannot assure the future success of these products or as to whether we will be able to recover our initial and ongoing investment in Noven Therapeutics and its products.

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The Noven Therapeutics acquisition may expose us to unexpected costs and liabilities.

Our acquisition of Noven Therapeutics entails an inherent risk that we could become subject to contingent or other liabilities, including liabilities arising from events or conduct pre-dating the acquisition. While the former owners of Noven Therapeutics have agreed to indemnify us for certain breaches of covenants, warranties and representations, our right to indemnity is limited to a maximum of $10 million and subject to time and other restrictions. These indemnification obligations may be inadequate to fully address any costs or damages we may incur, and any such costs or damages may have a material adverse effect on our business, financial condition and results of operations.

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 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 significantly 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 2002 (the year of publication of the results of the WHI study) to 2007. 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 condition 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 transdermal products, and could ultimately impair the commercial acceptance of our current and future transdermal 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 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

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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

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 historical profitability has been dependent on our equity in Novogyne s earnings, 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 that 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 Management 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 we have 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, we cannot assure 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, we cannot assure that we would be able to adequately perform the services currently being provided by Novartis or that we would not be adversely affected by the changes in capital and/or debt structure that likely would be required to finance the purchase.

We depend on Novartis to perform 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 also responsible for internal controls over financial reporting for Novogyne. As a result, 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 condition and results of operations of Novogyne and Noven.

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

We depend upon collaborative agreements with other pharmaceutical companies to obtain regulatory approval for and to market and sell certain of our transdermal 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 transdermal products. Under the terms of the Novogyne joint venture, Novartis is responsible for the distribution of Novogyne s products, including Vivelle-Dot®, and for selling Novogyne s products to its trade customers. For Daytrana,

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we have granted the exclusive marketing rights to Shire. Failure of Novartis, Shire or our other partners to adequately support our transdermal 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 transdermal products competitive with our transdermal products. 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 the earlier of April 2008 or 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 transdermal products. If one or more partners fails to pursue the marketing of our transdermal products as planned, or if marketing of any of those products is otherwise delayed, our business, financial condition 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 transdermal products or technologies.

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

Our supply agreements with our licensees for our transdermal products impose strict obligations on us with respect to the manufacture and supply of our transdermal products. Failure to comply with the terms of these supply agreements may result in our being unable to supply our transdermal products 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-Dot® has expired. Since the expiration of that supply agreement, the parties have continued to operate in accordance with certain of the supply agreement s pricing terms. We cannot assure that we and Novogyne will continue to operate under the supply agreement in accordance with certain of its pricing terms or that we will enter into a new supply agreement on satisfactory terms or at all. Due to our dependence on Novogyne, we may be unable to negotiate favorable business terms with them or resolve any dispute that we may be involved in with them in a favorable manner. Failure to continue operating in accordance with certain of the supply agreement s pricing terms could have a material adverse effect on our business, results of operations and financial condition. 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.

We face scale-up risks in the manufacture of new transdermal 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 transdermal products or otherwise meet supply requirements for these transdermal products, the success of our new transdermal product 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

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we experience manufacturing difficulties such as quality problems, yield deficiencies or similar issues, our overall manufacturing costs may be higher than anticipated.

We rely on third party manufacturers to supply us with our oral products. Failure of these third parties to comply with governmental regulations or our manufacturing and supply agreements or otherwise supply our oral products could negatively affect our financial condition and results of operations.

We rely upon third party manufacturers to manufacture and supply us with Pexeva® and the other products marketed and sold by Noven Therapeutics. We depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations and their agreements with us, and any production issues experienced by these third party manufacturers or delays in shipping products to us may affect our product supply and ultimately have a negative impact on our sales and profitability.

All manufacturers of pharmaceutical products sold in the United States must comply with the FDA s good manufacturing practices, and manufacturing operations and processes are subject to FDA inspection. Failure to comply with FDA or other governmental regulations can lead to the shutdown of a manufacturing facility, the seizure of a product distributed by that facility and other sanctions. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third party manufacturer, may require prior review and approval in accordance with the FDA s good manufacturing practices. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture of products, and if the third party manufacturers are unable to comply, they may be subject to regulatory action, civil actions or other sanctions.

In addition, our third party manufacturers may encounter difficulties, including problems involving:

inconsistent production yields;

difficulties in scaling production to commercial and validation sizes;

interruption of the delivery of raw materials required for the manufacturing process;

scheduling of plant time with other vendors or unexpected equipment failure;

potential catastrophes that could strike their facilities;

poor quality control and assurance or inadequate process controls; and

lack of compliance with regulations and specifications set forth by the FDA or other agencies.

Furthermore, we have no control over whether the third party manufacturers breach their agreements with us or whether they determine to terminate or decline to renew agreements with us. Defective products or other problems caused by our third party manufacturers could expose us to liability to others for which we may not have adequate recourse against our third party manufacturers. If there is poor manufacturing performance on the part of our third party manufacturers or we are contractually prohibited or unable to enter into agreements with additional manufacturers, if necessary, on commercially reasonable terms, we may not be able to meet commercial demand for Noven Therapeutics products or complete the development of, or successfully market, our products under development. Any of the above factors could interrupt our

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ability to sell our products and adversely affect our present and future sales margins, market share and product pipeline, as well as harm our overall business.

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

Certain raw materials and components used in the manufacture of our transdermal products, including essential polymer adhesives, are available from limited sources, and, in some cases, a single source. Without adequate approved supplies of raw materials or packaging supplies, our manufacturing operations relating to our transdermal products could be interrupted until another supplier is identified, our transdermal 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 transdermal products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, we cannot assure that such companies will not expand their restrictions to include our applications. Our business also faces the risk that third party suppliers may supply us with raw materials that do not meet required specifications, which, if undetected by us, could cause our transdermal 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 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.

Compliance with governmental regulation is critical to our business.

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 Miami manufacturing 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

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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. We cannot assure that Novartis will comply with these regulations or that any violation by Novartis will not have an adverse effect on us.

In addition, in recent years, several states and localities, including California, the District of Columbia, Maine, Massachusetts, Michigan, Minnesota, New Mexico, Ohio, Rhode Island, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failing to comply with these regulations are unclear. Furthermore, individual states, acting through their attorneys general, have become active, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. As a result of our acquisition of JDS, we market and sell our therapeutic products through our own sales force. We have recently implemented a compliance program designed to monitor and assist us in our compliance with these rules and regulations. Unless we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

Federal health care program anti-kickback statutes prohibit, among other things, knowingly and willfully soliciting or receiving any remuneration in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering, any good, facility or service that is reimbursable under Medicare, Medicaid or other federally financed health care programs. These statutes have been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, patients, purchasers and formulary managers, on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending any good, facility, or service which is reimbursable under Medicare, Medicaid or other federally financed health care program may be subject to scrutiny if such practices do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free products to customers with the expectation that the customers would bill federal programs for such products, reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates, engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses and submitting inflated best price information to the Medicaid Rebate Program.

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The majority of states also have statutes or regulations similar to the federal anti-kickback statutes and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would have an adverse impact on our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Decreased margins on sales of Daytrana may adversely impact our results of operations.

The price at which we sell Daytrana to Shire is determined in accordance with the terms of our 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 and our production yield of the product. If our production yields decrease or our costs of production for Daytrana increase, our margin on sales of the product and, consequently, our operating results will be adversely impacted. In particular, we have incurred and expect to incur in 2008 increased quality assurance costs related to the Daytrana release liner issue and our efforts to address the concerns raised by the FDA in the Form 483 and the warning letter. Our ability to produce Daytrana and continue to 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 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 our products, and competition is expected to intensify as more companies enter the markets in which we operate. Some of these companies are substantially larger than we are and have greater resources and greater experience in developing and commercializing pharmaceutical products than we do. As a result, they may succeed before us in developing competing technologies or obtaining governmental approvals for products.

Our transdermal products compete with other transdermal products, alternative dosage forms of the same or comparable chemical entities and non-drug therapies. We face 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 sprays, 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 final sales-based milestone payment under the Shire agreement depends on the sales levels achieved by Shire, which markets other ADHD products, including Vyvanse, an amphetamine pro drug for the treatment of ADHD. Other competitors marketing or developing ADHD products include Johnson &

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Johnson, Novartis, GlaxoSmithkline, Bristol-Myers Squibb, Abbott Laboratories, Celltech, and Lilly. 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. We cannot assure that our transdermal products and technologies will remain competitive. If we cannot maintain competitive transdermal 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, which would adversely impact our results of operations and financial condition.

Our oral products also participate in highly competitive markets. In the SSRI market and the market for the treatment of bipolar disorder, we compete against, among others, Lilly, GlaxoSmithKline, AstraZeneca and Pfizer, each of which is substantially larger and has greater financial resources than we do. In addition, Pexeva® faces competition in the SSRI market from generic versions of similar products and Lithobid® competes against generic versions of lithium products, including an AB-rated generic to Lithobid®. Manufacturers of generic products typically do not bear significant research and development or education and marketing development costs and consequently may be able to offer their products at considerably lower prices than we can offer our products.

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, our results of operations and financial condition would be adversely impacted.

Competitors may use legal, regulatory and legislative strategies to prevent or delay the launch of our products.

Competitors may pursue legislative and other regulatory or litigation strategies to prevent or delay the launch of our products. 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 s petition with the FDA; pursuing state legislative efforts to limit the substitution of generic versions of branded 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 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.

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

Pharmaceutical prices, including prices for our transdermal 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 transdermal products sold to Novartis Pharma for resale outside of the United States than for the same products sold to Novogyne for sale in the United States. In addition, the lower prices restrict Novartis Pharma s gross margin realized from selling our transdermal products. Because our transdermal products compete for sales and marketing resources with other Novartis Pharma products, including competitive HT products, we cannot assure that the relatively low gross margins generated from selling our transdermal products will not cause Novartis Pharma to focus its resources on other products or even not launch our transdermal products in certain countries. Novartis Pharma has launched Estradot® in the United Kingdom, France, Germany, Spain (without the benefit of government reimbursement) and in a number of smaller European countries. We cannot assure that Novartis Pharma will be successful in launching Estradot® in other countries. The profitability of sales in Europe may be negatively affected by parallel trade practices in the European Union whereby a licensed importer may take advantage of a price disparity between markets by purchasing our transdermal 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 2007, we experienced significant fluctuations in our quarterly operating results and we expect that revenues from product sales and 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. These factors include, without limitation: the timing of FDA approval and subsequent timing and success of any new transdermal or therapeutic product launch; the purchasing patterns of wholesale drug distributors; marketing efforts of our licensees relating to our transdermal products; fluctuations in sales and returns allowances, including those related to allowances for expiring products as well as product recalls; the inventory requirements of each licensee for our transdermal products; 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 transdermal product pricing of each licensee; the timing of certain royalty reconciliations and payments under our license agreements for our transdermal products; and the success of Shire s commercialization efforts. Our earnings may fluctuate because of, among other things, fluctuations in research and development expenses resulting from the timing of clinical trials and our efforts to bring our pipeline of therapeutic products to market. In addition, Novartis is entitled to an annual $6.1 million preferred return over our interest in Novogyne, which has had 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, which significantly increased as a result of the JDS acquisition.

Accounting principles generally accepted in the United States require us and Novogyne 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 amounts may not be recoverable. If the fair value is less than the carrying amount of the asset, a loss is recognized for the

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difference. Novogyne recorded the acquisition of the CombiPatch® product marketing rights at cost and tests this asset for impairment on a periodic basis. In addition, intangible assets in the form of patent development costs and goodwill from the acquisition of JDS form a significant portion of our total assets. If after testing the intangible assets and goodwill, we (or Novogyne) determine that these assets are impaired, then we (or Novogyne) would be required to write-down the impaired asset to fair value in the period when the determination is made. Such a write-down could have a material adverse effect on our results of operations.

We have invested a significant portion of our cash in auction rate securities, which subjects us to liquidity and investment risk. We could be required to record an impairment charge if the fair value of these investments were to decline.

At March 24, 2008, we held approximately $37.4 million in auction rate securities. Auction rate securities are floating rate debt securities with long-term nominal maturities, the interest rates of which are reset periodically (typically every 7 to 35 days) through a Dutch auction process. These periodic auctions have historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then-existing market rates or to liquidate their holdings by selling their securities at par value. In recent weeks as part of the ongoing credit market crisis, several auction rate securities from various issuers have failed to receive sufficient order interest from potential investors to clear successfully, resulting in auction failures. Historically, when investor demand was insufficient, the banks running the auctions would step in and purchase the remaining securities to prevent an auction failure. Recently, however, the banks have been allowing these auctions to fail.

During the period from February 14, 2008 to March 24, 2008, auctions failed for approximately $33.4 million of auction rate securities still owned by us at March 24, 2008. As a result, the securities related to the failed auctions could not be liquidated and now pay interest at a maximum rate allowed in the governing documents or indenture. We cannot predict when the liquidity of these securities will improve. Accordingly, as of December 31, 2007, we classified all of our auction rate securities as non-current ($32.8 million), with the exception of $17.6 million of securities that we liquidated subsequent to December 31, 2007 and a $4.0 million variable rate demand note supported by an irrevocable direct-pay letter of credit issued by a bank. Our liquidity will be adversely affected to the extent that auctions for our auction rate securities experience further failures. To enhance our liquidity position, we are currently seeking a credit facility, although we cannot assure that we will successfully obtain a credit facility on favorable terms or at all.

As of March 24, 2008, the auction rate securities that we hold are collateralized primarily by tax-exempt municipal bonds, and to a lesser extent, guaranteed student loans. We do not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. We believe our auction rate securities are of high credit quality, as approximately 75% of the investments carry an AA or AAA credit rating, and all are investment grade. We continue to monitor the market for auction rate securities although there is no current secondary market for such securities. If the fair value of the investments were to decline, management would be required to evaluate whether such decline is other than temporary in accordance with SFAS No. 115. The amount of impairment which is determined to be temporary would be included in stockholders equity as a component of other comprehensive income or loss. The amount of any such impairment loss which is determined to be other than temporary would be immediately recorded in the consolidated statement of operations. Such a non-cash impairment charge could materially and adversely affect our consolidated financial condition and results of operations. See Note 2 Summary of Significant

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Account Policies Investments Available for Sale , in the Notes to our consolidated financial statements for further information.

There are inherent uncertainties involved in the estimates, judgments and assumptions used in the preparation of our consolidated financial statements, and any changes in those estimates, judgments and assumptions could have a material adverse effect on our financial condition and results of operations.

The consolidated and condensed consolidated financial statements that we file with the SEC are prepared in accordance with United States generally accepted accounting principles (United States GAAP). The preparation of financial statements in accordance with United States GAAP involves making estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates we are required to make under United States GAAP include, but are not limited to, those related to revenue recognition, sales allowances, inventories and cost of goods sold, determining the useful life or impairment of goodwill and other long-lived assets, litigation settlements and related liabilities, and income taxes. We periodically evaluate estimates used in the preparation of the consolidated financial statements for reasonableness, including estimates provided by third parties. Appropriate adjustments to the estimates will be made prospectively, as necessary, based on such periodic evaluations. We base our estimates on, among other things, currently available information, market conditions, historical experience and various assumptions, which together form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although we believe that our assumptions are reasonable under the circumstances, estimates would differ if different assumptions were utilized and these estimates may prove in the future to have been inaccurate.

If our estimates for returned products are incorrect, there may be a materially adverse impact on our net revenues as well as an impact on our operating results.

In the pharmaceutical industry, customers are normally granted the right to return a product for a refund if the product has not been used by its expiration date or for a period of one year thereafter. Management is required to estimate the amount of product that will ultimately be returned pursuant to our return policy and to record a related reserve at the time of sale. These amounts are deducted from our gross revenues to determine our net revenues. We believe that we have sufficient data to estimate future returns at the time of sale. Management periodically reviews the allowances for returns and adjusts them based on actual experience. In order to reasonably estimate future returns, we analyze both quantitative and qualitative information including, but not limited to, actual return rates by product, the level of product in the distribution channel, expected shelf life of the product, product demand, the introduction of competitive or generic products that may erode current demand, our new product launches and general economic and industry wide indicators. There are inherent limitations in estimating future product returns due to the time lapse between sale and actual return of the product. If we over or under estimate the amount of product that will ultimately be returned, there may be a material impact to 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. We cannot assure that we will be issued patents for any of our patent applications, that any existing or future patents that we receive or

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license will provide competitive advantages for our products, or that we will be able to enforce successfully our patent rights. Specifically, Pexeva® and Mesafem are subject to a composition of matter patent that extends to 2017. However, recent Supreme Court case law (unrelated to our patent) may make it easier to challenge the validity of this patent on grounds of obviousness. If we are unable to enforce successfully our patent rights, including, without limitation, our patent rights relating to Pexeva® and Mesafem, our results of operations and financial condition may be adversely impacted.

Additionally, we cannot assure 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. The patents related to Vivelle-Dot® and other of our transdermal products are formulation patents and do not preclude others from developing and marketing products that deliver drugs transdermally or otherwise through non-infringing formulations. Furthermore, we cannot assure that any of our future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that our processes or products will not infringe upon the patents of third parties.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, manufacturers, suppliers, employees and consultants to protect our trade secrets, unpatented proprietary know-how and continuing technological innovation, but we cannot assure 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 condition and results of operations.

Our success depends, in part, on our ability to operate without infringing the proprietary rights of others, and we cannot assure 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. We cannot assure that we have identified, or that in the future we will be able to identify, all United States and foreign patents that may pose a risk of potential infringement claims.

In June 2007, Johnson-Matthey Inc. filed a complaint against us alleging that we were infringing one of its patents through our manufacture and sale of Daytrana and is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. We intend to vigorously defend this lawsuit, but the outcome cannot ultimately be predicted. See Item 3 Legal Proceedings.

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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 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 and SSRI markets, as well as the market for the treatment of bipolar disorder. In addition, managed care agreements established by Novartis could adversely affect Novogyne s financial results.

We are subject to chargebacks and rebates when our products are resold to or reimbursed by governmental agencies and managed care buying groups, which may reduce our net revenues and impact our operating results.

Chargebacks and rebates are the difference between the prices at which we sell our products to wholesalers and the price that third party payors, such as governmental agencies and managed care buying groups, ultimately pay pursuant to fixed price contracts. Medicare, Medicaid and reimbursement legislation or programs regulate drug coverage and reimbursement levels for most of the population in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. We record an estimate of the amount either to be charged back to us or rebated to the end-users at the time of sale to the wholesaler. Managed care organizations use these chargebacks and rebates as a method to reduce overall costs in drug procurement. We record an accrual for chargebacks and rebates based upon factors including current contract prices, historical chargeback and rebate rates and actual chargebacks and rebates claimed. The amount of actual chargebacks claimed could, however, be higher than the amounts we accrue, and could reduce our net revenues during the period in which claims are made. If we over or under estimate the level of chargebacks and rebates, there may be a material impact to our operating 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 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 condition or results of operations.

We may be exposed to product liability claims and we cannot assure that our insurance will be adequate.

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

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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 is currently named as a defendant in at least 26 additional lawsuits involving approximately 27 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® and CombiPatch®. Novogyne has been named as a defendant in one lawsuit in addition to the lawsuits referenced above. If any such claims against us or Novogyne 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 we cannot assure 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 a 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 condition and results of operations. Novogyne has a claims-made insurance policy with a $10.0 million aggregate limit, and as of December 31, 2007, Novogyne has recorded an insurance receivable of $6.8 million.

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

All of our transdermal products are manufactured at a single facility in Miami, Florida. An interruption of manufacturing resulting from regulatory issues (including in connection with the FDA warning letter described above), 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 condition or results of operations. Without our existing production facility, we would have no other means of manufacturing our transdermal 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 we cannot assure 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 impact on relations with our existing partners and customers resulting from our inability to produce transdermal products for them.

We use hazardous chemicals at our Miami manufacturing facility. 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.

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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 product 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. We cannot assure 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 condition or results of operations. Furthermore, it is possible that, in some cases, coverage may not be available at any price.

Our financial condition 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 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 condition 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. In particular, we have a national executive search underway for a permanent Chief Executive Officer to succeed Robert C. Strauss who retired in January 2008. 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 condition or results of operations.

Our stockholders rights plan, our corporate charter documents, Delaware law and our joint venture operating agreement 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

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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 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 joint venture 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® subject to the terms of Novartis prior arrangement with us, and Novogyne s other assets would be liquidated and distributed between us and Novartis in accordance with our and Novartis respective capital account balances as determined pursuant to the joint venture operating agreement. This dissolution provision could discourage one of the ten largest pharmaceutical companies from attempting to acquire us, which could have an adverse effect on the market price for our common stock.

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Your percentage of ownership and voting power and the price of our common stock may decrease as a result of events that increase the number of our outstanding shares.

As of December 31, 2007, we had the following capital structure (in thousands):

	No. of Shares
Common stock outstanding	24,560
Common stock issuable upon:	
Exercise of outstanding options/SSARs	3,511
Vesting of outstanding restricted stock units	6
Issuable shares	50
Exercise/vesting of options/SSARs and restricted stock units available for grant	1,168
Total common stock outstanding assuming exercise or issuance of the above	29,295

As of December 31, 2007, we had outstanding options/SSARs to purchase approximately 3,511,000 shares of common stock at exercise prices ranging from $9.08 to $36.24 (exercisable at a weighted average of $16.83 per share), of which approximately 2,098,000 were then vested and exercisable. We may conduct future offerings of our common stock or other securities with rights to convert the securities into shares of our common stock. Exercise of our outstanding options/SSARs into shares of our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power.

The market price for our common stock is volatile.

The market price for our common stock is volatile. During 2007, our common stock traded as low as $12.65 per share and as high as $27.80 per share. Any number of factors, including some that we do not control and some unrelated to our business or financial results, may have a significant impact on the market price for 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 patents or proprietary rights of us or 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.

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Item 2. Properties.

Our headquarters for both business segments (Noven Transdermals and Noven Therapeutics) and the manufacturing facility for our transdermal products are 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 (approximately $0.2 million at December 31, 2007) or, when fully depreciated, for $1.00. 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 transdermal products. The initial lease term expires in 2015 and the term may be extended for up to an additional 21 years pursuant to four renewal options for five years each and a one-time option to renew for one year. Our site includes 5 acres of vacant land that we own, which 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 transdermal products.

In addition, as part of the JDS acquisition in August 2007, we assumed the operating lease of 8,700 square feet of office space that JDS used for their operations in New York, New York. This lease expires in September 2010.

Our manufacturing facility for our transdermal products, as well as the site of our research and development activities and 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 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 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.

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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. One additional lawsuit was filed subsequent to December 31, 2007.

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 is currently named as a defendant in at least 26 additional lawsuits that include approximately 27 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.

In June 2007, Johnson-Matthey Inc. filed a complaint in the United States District Court, Eastern District of Texas against Noven and Shire alleging that we were infringing one of its patents through our manufacture and sale of Daytrana. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. We intend to vigorously defend this lawsuit, but the outcome of this lawsuit cannot ultimately be predicted.

We are a party to other pending legal proceedings arising in the normal course of business, none of which we believe is material to our consolidated financial condition 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, 2007.

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 24, 2008. Officers serve at the discretion of the Board of Directors. There is no family relationship between any of our executive officers or between any of our executive officers and any of our directors, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 42, has been with Noven since November 1998 and, since January 2008, has served as Executive Vice President and Interim Chief Executive Officer. From May 2005 to January 2008, he served as Noven s Senior Vice President Strategic

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Alliances. From January 2001 to September 2001, he served as Noven s Vice President, General Counsel and Corporate Secretary, and, from September 2001 to May 2005, he served as Noven s Vice President Strategic Alliances, General Counsel and 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 55, has been with Noven since February 1997 and, since November 2000, has served as Vice President Marketing and Sales. From 1981 through 1997, Mr. Jones 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 49, has been with Noven since March 1990 and, since June 2000, has served as Vice President and Chief Technical Officer. From 1986 to 1990, he served Paco Research Corp. as Manager Product Development. From 1983 to 1986, he served Key Pharmaceuticals, Inc. as Senior Research Engineer.

Michael D. Price. Mr. Price, age 50, was appointed Vice President and Chief Financial Officer of Noven in November 2007. Mr. Price retired from Bentley Pharmaceuticals, Inc. in September 2006 and was retired since that time through joining Noven in November 2007. Prior to his retirement, Mr. Price served as Chief Financial Officer, Vice President/Treasurer and Secretary of Bentley, where he was employed from March 1992 until September 2006. Mr. Price also served on Bentley s Board of Directors from 1995 until 2004. Mr. Price is a Certified Public Accountant licensed by the State of Florida.

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PART II

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

Our Common Stock is listed on the Nasdaq Global Select Market and is traded under the symbol NOVN. As of March 24, 2008, we had 242 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 our Common Stock as reported on the Nasdaq Global Select Market.

	High Price	Low Price
Fourth Quarter, 2007	$16.88	$12.65
Third Quarter, 2007	24.06	14.99
Second Quarter, 2007	26.15	22.23
First Quarter, 2007	27.80	21.68
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

The following table provides information with respect to our stock repurchases during the fourth quarter of 2007:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program[1]
October 1, 2007 to October 31, 2007				$ 19,876,238
November 1, 2007 to November 30, 2007				19,876,238
December 1, 2007 to December 31, 2007				19,876,238
Totals				$ 19,876,238

1 In September 2007, we announced a stock repurchase program authorizing the repurchase of up to $25.0 million of our common stock. During the

third quarter of 2007, Noven repurchased 322,345 shares of its common stock at an aggregate price of approximately $5.1 million. There is no expiration date specified for this program.

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The following graph shows the cumulative total return, assuming the investment of $100 on December 31, 2002 on an investment in each of Noven s common stock, the Russell 2000 Index and the Value Line Drugs Index (in either case, assuming reinvestment of dividends). The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock. We have not paid dividends to our stockholders since the inception and do not plan to pay dividends in the foreseeable future. The following graph and related information is being furnished solely to accompany this Form 10-K pursuant to Item 201(e) of Regulation S-K and shall not be deemed soliciting materials or to be filed with the SEC (other than as provided in Item 201), nor shall such information be incorporated by reference into any of our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, and irrespective of any general incorporation language in any such filing.

Comparison of Five-Year Cumulative Total Return*

Noven Pharmaceuticals, Russell 2000 Index And Value Line Drugs Index

(Performance Results Through 12/31/07)

	12/31/2002	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007
Noven Pharmaceuticals	$100.00	$164.79	$184.83	$163.92	$275.73	$150.38
Russell 2000 Index	$100.00	$145.37	$170.08	$175.73	$205.60	$199.96
Value Line Drugs Index	$100.00	$128.30	$127.15	$139.83	$161.06	$174.69

*Cumulative total return assumes reinvestment of dividends.

Source: Value Line, Inc.

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Item 6. Selected Financial Data.

The selected financial data presented below is derived from our audited consolidated 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 Consolidated Financial Statements and related notes appearing elsewhere in this Form 10-K (all amounts in thousands, except per share amounts).

	Years Ended December 31,				
	2007[1,2]	2006[2]	2005[3]	2004	2003
Statement of Operations Data:					
Net Revenues:					
Product revenues, net	$ 65,436	$ 48,326	$ 40,451	$ 36,871	$ 37,116
License and contract revenues	17,725	12,363	12,081	9,020	6,050
Total net revenues	83,161	60,689	52,532	45,891	43,166
Costs and Expenses:					
Cost of products sold	41,017	36,508	34,047	20,514	19,845
Acquired in-process research and development	100,150				
Research and development	13,978	11,454	13,215	9,498	7,719
Selling, general and administrative	39,571	21,701	16,915	17,271	15,858
Total costs and expenses	194,716	69,663	64,177	47,283	43,422
Loss from operations	(111,555)	(8,974)	(11,645)	(1,392)	(256)
Equity in earnings of Novogyne	35,850	28,632	24,655	17,641	17,094
Interest income, net	5,454	4,272	2,242	999	659
Income (loss) before income taxes	(70,251)	23,930	15,252	17,248	17,497
Provision (benefit) for income taxes	(24,875)	7,942	5,280	6,024	6,301
Net income (loss)	$ (45,376)	$ 15,988	$ 9,972	$ 11,224	$ 11,196
Basic earnings (loss) per share	$ (1.84)	$ 0.67	$ 0.42	$ 0.48	$ 0.50
Diluted earnings (loss) per share	$ (1.84)	$ 0.66	$ 0.42	$ 0.46	$ 0.49
Weighted average number of common shares outstanding:					
Basic	24,728	23,807	23,566	23,332	22,544
Diluted	24,728	24,252	23,981	24,305	22,989

Refer to footnotes on the following page.

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	December 31,				
	2007[1,2]	2006[2]	2005[3]	2004	2003
Balance Sheet Data:					
Current Assets:					
Cash and cash equivalents	$ 13,973	$ 9,144	$ 66,964	$ 93,958	$ 83,381
Short-term investments	21,565	144,455	17,900		
Other current assets	45,565	56,608	34,746	48,763	26,548
Non-current Assets:					
Property, plant and equipment, net	36,213	37,010	34,455	22,587	18,354
Investments, non-current[4]	32,835				
Investment in Novogyne	24,310	23,296	23,243	26,233	28,368
Net deferred tax asset, non-current	58,053	8,308	6,373	8,239	12,175
Intangible assets, net[5]	38,773	2,317	2,211	2,174	1,977
Goodwill[5]	14,734				
Deposits and other non-current assets	677	227	18	21	181
Total assets	$ 286,698	$ 281,365	$ 185,910	$ 201,975	$ 170,984
Current liabilities	$ 57,079	$ 29,386	$ 28,488	$ 45,372	$ 33,268
Non-current liabilities:					
Long-term obligations	8,438	279		121	
Deferred license and contract revenues	85,056	74,188	16,053	27,443	28,893
Other non-current liabilities	1,831	837	748		
Total liabilities	$ 152,404	$ 104,690	$ 45,289	$ 72,936	$ 62,161
Preferred stock					
Stockholders equity	$ 134,294	$ 176,675	$ 140,621	$ 129,039	$ 108,823

1 Financial results for 2007 included: (i) a one-time $100.2 million charge recorded in the 2007 third quarter for the portion of the JDS acquisition purchase price allocated to in-process research and development; (ii) a $3.3 million

charge recorded in the 2007 third quarter related to payments to Shire in connection with the voluntary market withdrawal of a portion of Daytrana product; (iii) an aggregate $3.3 million charge recorded in the 2007 fourth quarter related to separation arrangements with certain executive officers; and (iv) results of operations of Noven Therapeutics from the date of the JDS acquisition (August 14, 2007) through December 31, 2007.

[2] Financial results for 2007 and 2006 included $5.4 million and $3.3 million, respectively, in stock-based compensation expenses resulting from the adoption of SFAS No. 123 (R), Share-Based Payment effective January 1, 2006.

[3] Financial 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.

4 Investments, non-current at December 31, 2007 represents investments in auction rate securities. See Note 2, Summary of Significant Accounting Policies Investments Available-for-Sale.

5 Intangible assets, net and goodwill increased in 2007 as a result of the Noven Therapeutics acquisition.

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

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

An executive summary of our 2007 results of operations;

An overview of Noven and our Novogyne joint venture;

An overview of Noven Therapeutics;

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

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

An outlook that includes our current financial guidance for 2008;

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 2007 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 consolidated financial statements and related notes included in this Form 10-K.

Our financial results for 2007 include the results of operations of JDS from the date of acquisition (August 14, 2007) through December 31, 2007. JDS, now known as Noven Therapeutics, is a specialty pharmaceutical company focused in psychiatry and women s health, with a targeted sales force, psychiatry/CNS expertise, two marketed products, and a pipeline of new products in development. The JDS acquisition was an important part of Noven s transition from primarily a transdermal drug delivery company to an integrated specialty pharmaceutical company.

Our financial results for 2007 also include: (i) a one-time $100.2 million charge recorded in the 2007 third quarter for the JDS acquisition purchase price allocated to in-process research and development (IPR&D); (ii) a $3.3 million charge recorded in the 2007 third quarter related to payments to Shire in connection with the voluntary withdrawal of a portion of Daytrana product in the trade channel; and (iii) an aggregate $3.3 million charge recorded in the 2007 fourth quarter related to separation arrangements associated with the retirement of certain executive officers, including Robert C. Strauss, who retired from the position of President, Chief Executive Officer and Chairman effective January 2, 2008.

Including the impact of these substantial charges, we reported a net loss of $45.4 million ($1.84 loss per share) for 2007, compared to net income of $16.0 million ($0.66 diluted earnings per share) for 2006.

Our net revenues in 2007 were $83.2 million, an increase of 37% compared to $60.7 million reported in 2006. This increase reflects the recognition of $9.2 million in net revenues associated with our sales of Pexeva® and Lithobid® products through Noven Therapeutics, a full year of sales of Daytrana product, higher sales of our Vivelle-Dot® estrogen patch, and higher license revenues due to the amortization of additional Daytrana sales milestones.

Gross margin, as a percentage of product sales, was 37% in 2007 compared to 24% in 2006. Gross margin in 2007 benefited primarily from higher overall product revenues, greater manufacturing facility utilization, and the continuing benefit of cost reductions implemented in the third quarter of 2006. Gross margin in 2007 also benefited from a 66% gross margin percentage on sales of Noven Therapeutics products. Daytrana gross margin was negatively affected in 2007 by production and yield issues, a portion of the withdrawal costs referenced above, and increased quality assurance activities and costs.

Research and development expenses for 2007 increased 22% to $14.0 million, primarily due to higher clinical research activities at Noven Transdermals and to $1.5 million in research and development expenses at Noven Therapeutics.

Selling, general and administrative expenses for 2007 increased $17.9 million, or 82%, to $39.6 million, primarily reflecting the addition of $10.2 million in Noven Therapeutics expenses, 79% of which is selling and marketing related, $3.3 million in employee separation charges in the 2007 fourth quarter, $2.2 million in expenses associated with the voluntary market withdrawal of a portion of Daytrana product in the third quarter of 2007, and a $1.6 million increase in professional fees.

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We recognized $35.9 million in earnings from Novogyne in 2007, an increase of 25% compared to 2006. Net revenues at Novogyne increased 12% to $148.0 million in 2007, primarily due to increased sales of Vivelle-Dot®. Novogyne s gross margin percentage for 2007 increased slightly to 79%. Selling, general and administrative expenses increased 2% due to a $1.2 million increase in sample expenses. Novogyne s net income for 2007 increased 22% to $79.8 million compared to $65.3 million in the prior year.

At December 31, 2007, Noven had $14.0 million in cash and cash equivalents, $21.6 million in short-term investments, and $32.8 million in other investments (non-current). This compares with $9.1 million in cash and cash equivalents and $144.5 million in short-term investments at December 31, 2006. The net decrease primarily reflects the payment of $130.4 million in the acquisition of JDS Pharmaceuticals, tax payments of $23.7 million, and $5.1 million used in the third quarter to purchase shares under Noven s share repurchase program, partially offset by the receipt of an aggregate $50.0 million in Daytrana sales milestone payments, $28.8 million in distributions received from Novogyne, and $5.9 million received from Shire in connection with Noven s amphetamine patch development program. Noven s investments at December 31, 2007, consisted of $54.4 million in auction rate securities, $32.8 million of which have been classified as non-current on Noven s consolidated balance sheet following failed auctions occurring since mid-February 2008.

Total prescriptions for Vivelle-Dot® increased 4% in 2007 compared to 2006, and total prescriptions for Novogyne s products, taken as a whole, increased 2%. By comparison, the overall U.S. HT market declined 8% for the same period. Total prescriptions for Daytrana (launched in June 2006) increased 165% in 2007 (the first full year of sales) compared to 2006, while prescriptions for ADHD stimulant therapies as a class increased 8% in 2007 compared to 2006. Comparing the 2007 fourth quarter to the 2006 fourth quarter, Daytrana prescriptions increased 10%, while prescriptions for the class increased 7% for the same period. The market share of Daytrana remained substantially unchanged during 2007. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 41% in 2007 compared to 2006. Total prescriptions for Pexeva® increased 16% in 2007 compared to 2006, while for the same period prescriptions for the selective serotonin re-uptake inhibitor (SSRI) class increased 2%.

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Overview of Noven and our Novogyne Joint Venture

Our transdermal business is focused on developing advanced transdermal patches. We presently derive the majority of our transdermal revenues from sales of transdermal patches for use in menopausal HT. In the United States, our HT products are marketed and sold by Novogyne Pharmaceuticals, the joint venture that we formed with Novartis in 1998. Our business, financial condition and results of operations are significantly dependent upon Novogyne and its marketing of our HT products in the United States. A discussion of Novogyne s results of operations and their impact on our results can be found under the caption Results of Operations Equity in Earnings of Novogyne. In all countries other than the United States, Canada and Japan, we have licensed the marketing rights to these products to Novartis Pharma, which is an affiliate of Novartis.

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

Novartis is entitled to an annual $6.1 million preferred return from Novogyne, which has the effect of reducing our share of Novogyne s income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne s income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne s income was $35.9 million, $28.6 million and $24.7 million in 2007, 2006, and 2005, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne s Management Committee. Accordingly, the amount of cash that we receive from Novogyne in any period is typically not the same as the amount of income we recognize from Novogyne for that period. In 2007, 2006 and 2005, we received $28.8 million, $26.4 million and $26.2 million, respectively, in distributions from Novogyne, which, in addition to the Daytrana milestone payments received from Shire, accounted for a substantial portion of our net cash flows generated by operating activities for these periods. We expect that for the next several years a substantial portion of our earnings will be generated through our interest in Novogyne and a substantial portion of our cash flow will also be generated through our interest in Novogyne (in addition to any milestone payments we may receive from Shire). Any failure by Novogyne to remain profitable or to continue to make distributions would have a material adverse effect on our consolidated results of operations and financial condition.

Overview of Noven Therapeutics

Noven Therapeutics is a specialty pharmaceutical company that currently markets two branded prescription psychiatry products and is advancing several developmental products in psychiatry and women s health. We will seek to leverage Noven Therapeutics marketing and sales infrastructure with next-generation psychiatry/CNS products, and with complementary products that we will seek to develop and/or acquire. Noven Therapeutics currently marketed products consist of:

Pexeva®, an SSRI antidepressant indicated for major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder.

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Lithobid®, an extended release lithium product, is the only branded lithium product sold in the United States. Lithobid® is indicated for the maintenance of bipolar disorder and the treatment of related manic episodes.

In addition to marketing and selling these branded products, Noven Therapeutics is advancing a pipeline of therapeutic products in development, including Stavzor, a proprietary enteric-coated soft gelatin capsule delivery system for use in the treatment of bipolar disorder and epilepsy and in migraine therapy that we expect to launch in the second half of 2008, Lithium QD, a once-daily lithium product under development and Mesafem, a non-hormonal therapy for the treatment of vasomotor symptoms associated with menopause that is under development. To bring Noven Therapeutics pipeline of products under development to market, we plan to increase our research and development expenses significantly beginning in 2008. See Management s Discussion and Analysis of Financial Condition and Results of Operations Outlook.

Certain Items that May Affect Historical or Future Comparability

Set forth below are certain items that may affect the historical or future comparability of our consolidated results of operations and financial condition. Such disclosure is not intended to address every item that may affect the historical or future comparability of our consolidated results of operations or financial condition and such disclosure should be read in conjunction with the discussion and analysis of our consolidated results of operations, liquidity and capital resources and outlook appearing elsewhere in this Item 7.

Acquisition of JDS Pharmaceuticals, LLC in 2007

We acquired JDS on August 14, 2007 (the Closing Date). The total purchase price for the JDS acquisition consisted of $125.0 million cash paid at closing, approximately $5.4 million of transaction costs consisting primarily of fees paid for financial advisory, legal, valuation and accounting due diligence services, and approximately $0.5 million in connection with non-competition agreements entered into with two executives of JDS in connection with the acquisition. We funded the acquisition from the sale of short-term investments. We accounted for the acquisition of JDS using the purchase method of accounting. The purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by approximately $14.7 million, which has been recorded as goodwill, all of which is deductible for tax purposes. The primary factors that contributed to the recognition of goodwill in our acquisition of JDS are the intellectual capital of the skilled sales and marketing personnel and an organized experienced pharmaceutical sales force that is leveragable, neither of which meet the criteria for recognition as an asset separate from goodwill. The total purchase price for the acquisition has been allocated to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the Closing Date, which increased our assets and liabilities on the Closing Date as follows (amounts in thousands):

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Current assets, including cash of $0.6 million	$ 8,268
Property and equipment	362
Intangible assets:	
Acquired in-process research and development	100,150
Identifiable intangible assets	38,547
Goodwill	14,734
Other assets	163
Accrued expenses and other current liabilities	(16,088)
Long-term obligation assumed	(3,711)
Contingent milestones assumed	(11,500)
Total purchase price	$ 130,925

As noted in the table above, $100.2 million of the purchase price has been allocated to IPR&D, which was charged to operations immediately following the completion of the acquisition in 2007. The IPR&D expense resulted in a significant loss in 2007.

The $38.5 million in identifiable intangible assets relates to: (i) intellectual property rights associated with Noven Therapeutics products approved by the FDA; (ii) favorable lease intangible asset; and (iii) non-competition agreements with two former executives of JDS. At December 31, 2007, the carrying amount of Noven s intangible assets (excluding goodwill, but including certain patent development costs unrelated to the JDS acquisition) totaled $38.8 million. Noven estimates that the annual amortization expense for intangible assets held at December 31, 2007 for each of the five years through 2012 will be as follows (amounts in thousands):

	Years Ending December 31,				
	2008	2009	2010	2011	2012
Cost of goods sold:					
Intellectual property	$ 4,095	$ 4,012	$ 3,965	$ 3,904	$ 3,888
Selling, general and administrative:					
Non-competition agreements	221	171	55		
Favorable lease	115				
	336	171	55		
Total	$ 4,431	$ 4,183	$ 4,020	$ 3,904	$ 3,888

We are required to test our intangible assets with indefinite lives, including our goodwill, for impairment on an annual basis or more frequently if indicators of impairment arise. We are required to test our intangible assets with finite lives if events or changes in circumstances indicate that the asset might be impaired. If after testing the intangible assets and goodwill, we determine that these assets are impaired, then we would be required to write-down the impaired asset to fair value in the period when the determination is made.

The assumed long-term obligation of $3.7 million was paid in 2007 based on an analysis of favorable early payment discount. The $11.5 million contingent milestones assumed are for contingent sales milestones related to JDS acquisition of Pexeva® from Synthon, which are payable upon the achievement of specified future sales levels of the product.

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Daytrana

We have received reports from some consumers concerning the difficulty of removing the release liner from Daytrana patches. In the first quarter of 2007, we, together with Shire, implemented enhancements to the Daytrana release liner intended to improve ease of use of the patch. While the enhanced release liner has reduced the level of consumer reports, we continue to seek further enhancements to the Daytrana release liner to improve the ease of use of the patch. Throughout 2007 Daytrana s market share has remained substantially unchanged.

In July 2007, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. The majority of the observations in the Form 483 related to the Daytrana patch and difficulties experienced by some patients in removing the release liner, including certain product lots that utilize the enhanced release liner. In July 2007, we submitted to the FDA our response to the Form 483.

In the third quarter of 2007, Shire initiated two voluntary market withdrawals of a portion of the Daytrana product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana patches. We paid Shire $3.3 million in February 2008 related to the withdrawals. These costs were charged to operations in the third quarter of 2007 as follows: (i) $0.8 million was reflected as a reduction of revenues; (ii) $0.3 million was recorded as an increase to cost of goods sold; and (iii) $2.2 million was recorded as selling, general and administrative expense.

In January 2008, Noven received a warning letter from the FDA in connection with the FDA s July 2007 inspection of our manufacturing facilities. In the warning letter, the FDA cites Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana s release liner; and (ii) data supporting the peel force characteristics of Daytrana s enhanced release liner throughout the product s shelf life. We submitted our response to the warning letter on January 30, 2008; however, no assurance can be given that our response will be acceptable to the FDA or satisfactorily address the FDA s concerns.

Our business will be significantly harmed if we are unable to adequately resolve the issues raised by the FDA in the warning letter as well as the production and other issues involving Daytrana. For a detailed discussion of the risks and uncertainties facing Daytrana, please see the risk factor discussion beginning on page 26 of this Form 10-K.

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Results of Operations

With the addition of Noven Therapeutics, our business is now comprised of two reportable segments distinguished along product categories: (i) Noven Transdermals, which currently engages in the research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products, including product sales to Shire and Novogyne as well as our equity in earnings of Novogyne; and (ii) Noven Therapeutics, which currently engages in the development, marketing, sales and distribution of pharmaceutical products.

Prior to the acquisition of JDS on August 14, 2007, we operated exclusively in the Transdermals segment. Following the acquisition, in accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, we began to separately report information for the Therapeutics segment. We currently evaluate segment performance based on segment contribution, which consists of segment gross margin less direct research and development expenses and direct selling expenses, plus (in the case of Transdermals) our equity in earnings of Novogyne. Corporate general and administrative expenses, interest income and the immediate expensing of acquired IPR&D have not been allocated to our operating segments. Our results by segment are presented in the table below for the year ended December 31, 2007. The contribution of our Transdermals segment includes the impact of $35.9 million recognized as equity in earnings of Novogyne. The results of our Therapeutics segment are from the Closing Date through December 31, 2007. The negative contribution of our Therapeutics segment reflects the impact of significant selling and marketing expenses in support of Noven Therapeutics products and sales and marketing infrastructure, which infrastructure we expect to leverage in future periods through the commercialization of additional products.

	Year Ended December 31, 2007		
	Transdermals	Therapeutics	Total
(in thousands of dollars):			
Product revenues	$ 56,223	$ 9,213	$ 65,436
License and contract revenues	17,725		17,725
Net revenues	73,948	9,213	83,161
Cost of products sold	(37,871)	(3,146)	(41,017)
Research and development	(12,473)	(1,505)	(13,978)
Selling and marketing	(1,059)	(8,101)	(9,160)
Equity in earnings of Novogyne	35,850		35,850
Segment contribution	$ 58,395	$ (3,539)	54,856
Unallocated income (expense):			
Acquired IPR&D			(100,150)
General and administrative			(30,411)
Interest income, net			5,454
Loss before income taxes			$ (70,251)

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Revenues:

The following table summarizes our net revenues by segment and type (dollar amounts in thousands):

	Years Ended December 31,				
	2007	% change	2006	% change	2005
Noven Transdermals					
Novogyne:					
Product sales	$ 22,425	14%	$ 19,714	-1%	$ 19,910
Royalties	7,458	9%	6,845	6%	6,444
	29,883	13%	26,559	1%	26,354
Third Parties:					
Product sales	26,000	21%	21,422	55%	13,779
Royalties	340	-1%	345	8%	318
	26,340	21%	21,767	54%	14,097
Total product revenues	56,223	16%	48,326	19%	40,451
License and contract revenues	17,725	43%	12,363	2%	12,081
Total Transdermals	73,948	22%	60,689	16%	52,532
Noven Therapeutics					
Third Parties:					
Product sales	9,213	N/A			
Net Revenues	$ 83,161	37%	$ 60,689	16%	$ 52,532

Net Revenues

As described in more detail below, the 37% increase in net revenues for 2007 as compared to 2006 was primarily attributable to full year sales of Daytrana and an increase in license revenue associated with that product. Aggregate sales to Novogyne increased primarily due to increased sales of Vivelle-Dot®. In addition, revenues in 2007 benefited from the inclusion of $9.2 million in Pexeva® and Lithobid® sales since August 14, 2007, the date of our acquisition of JDS.

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

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.

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The $3.3 million increase in product revenues from Novogyne for 2007 as compared to 2006 primarily related to a $3.9 million increase in sales of Vivelle-Dot®, of which $1.9 million related to trade product sales due to increased prescription trends, $0.9 million related to the timing of orders from Novogyne for samples of Vivelle-Dot® and $1.1 million related to a price increase. Royalties increased $0.6 million due to increased sales by Novogyne for 2007. Revenues from Novogyne in 2006 were relatively consistent with 2005.

As noted below under Novogyne Net Revenues , Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies and the timing of orders by these customers is difficult to predict and can lead to significant variability in trade customers ordering patterns. As a result, there may be significant period-to-period variability in Novogyne s ordering patterns from Noven.

Product Revenues Third Parties

Product revenues third parties consists of: (i) sales of Estradot®, Estalis® and Menorest hormone therapy patches 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; (ii) sales of Daytrana to Shire for commercial resale in the United States; and (iii) beginning on August 14, 2007, Noven s commercial sales of Pexeva® and Lithobid® to trade customers, including wholesalers, distributors and chain pharmacies.

The $13.8 million increase in product revenues third parties for 2007 as compared to 2006 primarily related to $4.7 million increase in volume sales of Daytrana, the addition of $9.2 million in Pexeva® and Lithobid® revenues and a $1.3 million increase related to HT product pricing with Novartis Pharma. Daytrana product sales in 2007 were $13.4 million compared to $8.6 million in 2006. Sales of Daytrana commenced in the second quarter of 2006. The increase related to HT product pricing was primarily due to the recognition of a higher price reconciliation payment received from Novartis Pharma in 2007 as compared to 2006. 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. These increases were partially offset by declines of $0.7 million and $0.5 million in sales volume of Menorest and Femiest®, respectively. The decline in Menorest is attributable to the continued transition from Menorest to Estradot®, while we believe the decline in Femiest® is due to the timing of orders.

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 sales of Daytrana, reflecting the initial product launch during 2006. This increase was partially offset by a $0.9 million decline in the recognition of the price reconciliation payments received from 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®.

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License and Contract Revenues

License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements. Contract revenues consist 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 increased $6.9 million for 2007 as compared to 2006, mostly attributable to an increase of $8.1 million in amortization of milestone payments received from Shire related to the license of Daytrana. The $8.1 million increase reflects full-year amortization of the $50.0 million approval milestone compared to two quarters in 2006, full-year amortization of the $25.0 million sales milestone received in the first quarter of 2007 as well as six-months amortization of the $25.0 million sales milestone received in the third quarter of 2007. In 2006, we benefited from the recognition of $1.0 million in deferred license revenues related to a one-time non-refundable payment from a third party. Contract revenues declined $1.5 million for 2007 as compared to 2006, primarily reflecting a decline in contract work performed.

License revenues increased $0.8 million for 2006 as compared to 2005 primarily due to the recognition of $5.9 million in amortization of milestone payments related to our Daytrana license to Shire 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 revenues recognized in 2005 related to our fentanyl agreement with Endo Pharmaceuticals, Inc. (Endo), the majority of which was recognized in the fourth quarter of 2005 due to the termination of the agreement with Endo upon the FDA s decision to cease review of our fentanyl patch application. Contract revenues declined $0.6 million for 2006 as compared to 2005 due to a decline in contract work performed.

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Gross to Net Revenues

We record revenues net of sales allowances for rebates, chargebacks, cash and other discounts, as well as sales returns allowances. The following table sets forth the reconciliation of our gross revenues to net revenues for the three years ended December 31, 2007 for both Noven Transdermals and, for the period from August 14, 2007 to December 31, 2007, for Noven Therapeutics (dollar amounts in thousands):

	2007	% of gross revenues	2006	% of gross revenues	2005	% of gross revenues
Noven Transdermals:						
Gross revenues	$ 74,903	100%	$ 60,982	100%	$ 52,565	100%
Sales returns allowances	955	1%	293	0%	33	0%
Net revenues	$ 73,948	99%	$ 60,689	100%	$ 52,532	100%
Noven Therapeutics:						
Gross revenues	$ 14,579	100%				
Cash discounts	285	2%				
Medicaid, Medicare & State program rebates and credits including prescription drug saving cards, vouchers	3,289	23%				
Chargebacks	351	2%				
Wholesaler Fees	775	5%				
Sales allowances	4,700	32%				
Sales returns	666	5%				
Sales and returns allowances	5,366	37%				
Net revenues	$ 9,213	63%				

Sales returns allowances consist of changes in allowances for returns for product recalls and/or products voluntarily withdrawn from the market for Noven Transdermals and changes in allowances for returns of expiring product for Noven Therapeutics. During 2007, sales returns allowances for Noven Transdermals increased $0.7 million, primarily due to Shire s voluntary market withdrawals of certain Daytrana product.

Gross Margin:

This section discusses gross margins relating to our product revenues: (i) across all of our products (Overall Gross Margin); (ii) on our Transdermals product revenues from Novogyne (Gross Margin Novogyne), which for accounting purposes is considered a related party; (iii) on our Transdermals product revenues from third parties (Gross Margin Third Parties); and (iv) on

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our Therapeutics products. Product revenues from third parties include HT product sales to Novartis Pharma for resale primarily outside the United States and Japan, as well as Daytrana product sales to Shire. Therapeutics product revenues include sales of Pexeva® and Lithobid® to trade customers starting on August 14, 2007.

The allocation of overhead costs impacts our determination of gross margins for each of our products. Overhead costs, which were in excess of $24.0 million in 2007, include salaries and benefits, supplies and tools, equipment costs, depreciation and amortization, 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):

	Years Ended December 31,					
	2007		2006		2005	
Noven Transdermals						
Novogyne:						
Product revenues	$ 29,883		$ 26,559		$ 26,354	
Cost of products sold	13,683		14,102		13,547	
Gross profit	16,200	54%	12,457	47%	12,807	49%
Third parties:						
Product revenues	26,340		21,767		14,097	
Cost of products sold	24,188		22,406		20,500	
Gross profit (loss)	2,152	8%	(639)	-3%	(6,403)	-45%(1)
Total Noven Transdermals						
Product revenues	56,223		48,326		40,451	
Cost of products sold	37,871		36,508		34,047	
Gross profit	18,352	33%	11,818	24%	6,404	16%
Noven Therapeutics						
Product revenues	9,213					
Cost of products sold	3,146					
Gross profit	6,067	66%				
Total Company						
Product revenues	65,436		48,326		40,451	
Cost of products sold	41,017		36,508		34,047	
Gross profit	$ 24,419	37%	$ 11,818	24%	$ 6,404	16%(1)

(1) The year ended December 31, 2005 includes a $9.9 million charge for inventory write-offs and disposal costs following the FDA s decision to cease review of our fentanyl patch ANDA. Excluding the impact of this charge, third party gross profit was $3.5 million or 25%, and total company gross profit was $16.3 million or 40% in 2005. Gross profit excluding our 2005 fentanyl charge is a non-GAAP measure. Management uses this non-GAAP measure to evaluate our ongoing business and to meaningfully compare operating results between years. We believe investors find this information useful for the same purpose. Gross profit excluding the fentanyl charge is not a

substitute for GAAP-basis gross profit as presented in the table.

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In general, Noven Therapeutics products have higher gross margins than our other products because we sell these products directly to trade customers at wholesale and commercial prices. Our sales of HT products to Novogyne for resale in the United States have a higher gross margin than our other transdermal 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 the factors described below.

As noted in the tables above, Overall Gross Margin improved significantly in 2007 compared to 2006. Overall Gross Margin in 2007 benefited from: the addition of our Pexeva® and Lithobid® products, which had net sales of $9.2 million and related cost of products sold of $3.1 million, resulting in a gross margin of 66% for those products; significantly higher product revenues due to full-year sales of Daytrana; higher facility utilization for our transdermal products, which contributed to improved overhead absorption; cost savings associated with our cost reduction program initiated in the third quarter of 2006; and a $1.3 million increase in price reconciliation payments relating to international sales of our HT products for 2007 as compared to 2006, which payments increase product revenues without increasing costs.

Overall Gross Margin in 2007 was negatively affected by our gross margin on Daytrana product sales. 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 and to fully utilize our facilities. For 2007, Daytrana product revenues were $13.4 million (which reflects a $0.8 million adjustment in allowances for returns at Noven related to the Daytrana market withdrawal) and cost of products sold related to Daytrana was $14.8 million, resulting in negative gross margin for the product. Daytrana gross margin was negatively affected in 2007 by yield issues and increased costs related to delays in obtaining a supply of the active methylphenidate ingredient (AMI) during the year, quality assurance costs and the voluntary market withdrawals. In 2008, we expect to incur increased quality assurance costs related to our continued efforts to address the issues raised by the FDA in the July 2007 Form 483 and January 2008 warning letter, and a significant portion of these continuing costs will be allocated to Daytrana, which will negatively affect the gross margin on sales of this product in 2008.

As noted in the tables above, excluding the fentanyl charge, Overall Gross Margin declined significantly in 2006 as compared to 2005. During 2006, our Overall Gross Margin was materially and adversely affected by start-up expenses associated with commencing production of Daytrana, and production inefficiencies including lower than desired yields and increased costs associated with meeting critical launch timelines. In addition, the cost of the 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. To a lesser extent, Overall Gross Margin in 2006 was also negatively affected by

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increased personnel and other resources dedicated to quality control in our HT operations and by lower production volume in our HT business due to the timing of orders.

Our expectations for gross margins in future periods are addressed under Outlook below.

Operating Expenses:

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

	Years Ended December 31,				
	2007	% Change	2006	% Change	2005
Research and development	$ 13,978	22%	$11,454	(13%)	$13,215
Acquired in-process research and development	100,150	N/M			
Selling, general and administrative	39,571	82%	21,701	28%	16,915

N/M Not Meaningful

Research and Development

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

The $2.5 million increase in research and development expenses for 2007 as compared to 2006 was primarily due to a $1.9 million increase in clinical research costs on developmental products for Noven Transdermals and $1.5 million in Noven Therapeutics expenses since the Closing Date of the acquisition. These increases in 2007 were partially offset by a $1.0 million decline in development engineering expenses primarily related to Daytrana prior to the product s launch in the second quarter of 2006.

The $1.8 million decline in 2006 as compared to 2005 was primarily attributable to a $3.2 million decline in development engineering expenses related to our Daytrana 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.

Acquired In-Process Research and Development

As discussed above, we charged $100.2 million to operations in 2007 representing the portion of the purchase price allocated to IPR&D in our acquisition of JDS. This amount represents the value assigned to projects that have been initiated and achieved material progress but: (i) have not yet reached technological feasibility or have not yet reached the appropriate regulatory approval; (ii) have no alternative future use; and (iii) the fair value is estimable with reasonable certainty.

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Selling, General and Administrative

Selling, general and administrative expenses increased $17.9 million for 2007 as compared to 2006 primarily due to the addition of $10.2 million of Noven Therapeutics expenses since the Closing Date of the acquisition, primarily related to sales and marketing of Pexeva® and Lithobid®. In addition, Noven Transdermals selling, general and administrative expenses increased $7.7 million, due in part to a $4.2 million increase in compensation expenses, of which $3.3 million related to separation arrangements with certain executive officers. Also contributing to the increase was $2.2 million in costs associated with the voluntary market withdrawals of Daytrana and a $1.6 million increase in professional fees.

The $4.8 million increase in selling, 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 No. 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 we implemented in 2006. 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.

Other Income and Expenses:

Interest Income

Interest income increased $1.2 million, or 28%, in 2007 as compared to 2006. This increase was primarily attributable to an increase in cash available for investment due to our receipt from Shire of sales milestone payments of $25.0 million in March 2007 and $25.0 million in August 2007. These cash increases were partially offset by the $130.4 million in cash consideration related to the JDS acquisition, which decreased our cash available for investment in the third and fourth quarters of 2007.

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 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.

Income Taxes

Our effective tax rate was 35%, 33% and 35% for 2007, 2006 and 2005, respectively.

The increase in our effective tax rate for 2007 as compared to 2006 related primarily to a higher percentage of our income that was subject to state income taxes and lower tax-free interest income as a percentage of our total loss due to the sale of investments for payment of the purchase price of our acquisition of JDS and our IPR&D expense related to the JDS acquisition.

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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 liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. The acquisition of JDS resulted in a significant increase in our deferred income tax assets, primarily due to the fact that the $100.2 million IPR&D expense recognized in 2007 is not immediately deductible for tax purposes. As of December 31, 2007, we had a net deferred tax asset of $65.7 million compared to $12.7 million at December 31, 2006. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics files separate state income tax returns in states where it has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. We expect that Noven Therapeutics will incur taxable losses in the next few years due to future expected clinical trial expenditures related to product development. These expected taxable losses create negative evidence indicating the need for a valuation allowance at December 31, 2007. We recorded a valuation allowance of $3.2 million for the year ended December 31, 2007, due to uncertainties in realizing these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future Noven Therapeutics profitability that these state deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

The decrease in our effective tax rate for 2006 as compared to the prior year relates primarily to higher 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 2005 that did not recur in 2006.

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 2007, 2006 and 2005 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 consolidated Statements of Operations.

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

	Years Ended December 31,				
	2007	% Change	2006	% Change	2005
Gross revenues [1]	$ 171,347	11%	$ 154,901	13%	$ 136,901
Sales allowances	21,912	27%	17,226	20%	14,408
Sales returns allowances	1,447	N/M	5,732	N/M	936
Sales and returns allowances	23,359	2%	22,958	50%	15,344
Net revenues	147,988	12%	131,943	9%	121,557
Cost of sales	31,204	3%	30,149	5%	28,696
Gross profit	116,784	15%	101,794	10%	92,861
Gross margin percentage	79%		77%		76%
Selling, general and administrative expenses	38,083	2%	37,318	5%	35,568
Income from operations	78,701	22%	64,476	13%	57,293
Interest income	1,145	36%	841	82%	461
Net income	$ 79,846	22%	$ 65,317	13%	$ 57,754
Noven s equity in earnings of Novogyne	$ 35,850	25%	$ 28,632	16%	$ 24,655

N/M Not Meaningful

[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.

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 $16.4 million for 2007 as compared to 2006. By product, Vivelle-Dot® increased $17.9 million while Estradot®, Vivelle® and CombiPatch® declined $0.8 million, $0.6 million and $0.1 million respectively. The $17.9 million Vivelle-Dot® increase consisted of an $11.3 million increase related to pricing and a $6.6 million increase from higher unit sales due to increased product demand and to the timing of orders. The decline in Estradot® was attributable to the timing of orders. The decline in Vivelle®, the first generation estrogen patch, is attributable to a $1.0 million decline due to lower unit sales resulting from product maturity and the continuing market transition to Vivelle-Dot®, partially offset by a $0.4 million increase related to pricing. The decline in CombiPatch® results from a $1.4 million decrease due to lower unit sales as the market for combination therapies continues to decline, and the impact of a competitive product. The CombiPatch® decline was partially offset by a $1.3 million increase related to pricing of the product.

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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 an $11.2 million increase from higher unit sales due to an increase in prescriptions as well as the timing of orders, and an $8.0 million increase related to pricing. Vivelle®, the first generation estrogen patch, declined by $1.2 million due to lower unit sales resulting from product maturity and the planned discontinuation of the product, partially offset by a $0.3 million increase related to pricing. CombiPatch® revenues declined $1.2 million due to lower 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 of the product.

The following table describes Novogyne s sales and returns allowances for the years ended December 31, 2007, 2006 and 2005 (dollar amounts in thousands) **:**

	2007	% of gross revenues	2006	% of gross revenues	2005	% of gross revenues
Gross revenues	$ 171,347	100%	$ 154,901	100%	$ 136,901	100%
Managed health care rebates	13,226	8%	10,117	7%	8,018	6%
Cash discounts	3,387	2%	3,042	2%	2,690	2%
Medicaid, Medicare & State program rebates and credits including prescription drug saving cards	1,637	1%	981	1%	938	1%
Chargebacks, including hospital chargebacks	1,298	1%	1,032	1%	970	1%
Other discounts	2,364	1%	2,054	1%	1,792	1%
Sales allowances	21,912	13%	17,226	11%	14,408	11%
Sales returns allowances	1,447	1%	5,732	4%	936	1%
Sales and returns allowances	23,359	14%	22,958	15%	15,344	11%
Net revenues	$ 147,988	86%	$ 131,943	85%	$ 121,557	89%

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, 2007, 2006 and 2005 was as follows (amounts in thousands):

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	2007	2006	2005
Current year provisions for returns of expiring product	$ 3,372	$ 4,342	$ 3,384
Adjustment to prior year provisions for returns of expiring product	(1,925)	1,390	(2,385)
Benefits for returns for product recalls			(63)
Sales returns allowances	$ 1,447	$ 5,732	$ 936
Actual returns for expiring product	(3,349)	(3,962)	(3,897)
Actual returns for product recalls			(40)
Total actual returns	$ (3,349)	$ (3,962)	$ (3,937)

The decrease in sales returns allowances as a percentage of gross revenues for 2007 as compared to 2006 was primarily related to lower actual returns of CombiPatch in the current period. The higher returns of CombiPatch® in the prior period primarily related to returns of a superseded packaging configuration.

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® due to a superseded packaging configuration, 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.

Novogyne Gross Margin

The two percentage point gross margin increase for 2007 as compared to 2006 was primarily related to higher pricing, especially for Vivelle-Dot®, and to an aggregate decrease in sales returns allowances due to lower returns of CombiPatch®. Novogyne s gross margin was consistent for 2006 as compared to 2005.

Novogyne Selling, General and Administrative

Novogyne s selling, general and administrative expenses increased $0.8 million for 2007 as compared to 2006 due to a $1.2 million increase in sample expenses and a $0.5 million increase in sales, marketing and advertising expenses. These increases were partially offset by a $0.9 million decline in HT litigation expenses.

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.

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Liquidity and Capital Resources:

As of December 31, 2007 and December 31, 2006, Noven had the following (amounts in thousands):

	December 31,	
	2007	2006
Cash and cash equivalents	$13,973	$ 9,144
Short-term investments	21,565	144,455
Working capital	24,024	180,821

Short-term investments and working capital significantly decreased during 2007 as a result of: (i) the acquisition of JDS on August 14, 2007; and (ii), the reclassification to non-current of $32.8 million of investments in auction rate securities, as discussed in Item 7A, Quantitative and Qualitative Disclosures about Market Risk.

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

	Years Ended December 31,		
	2007	2006	2005
Cash flows:			
Operating activities	$ 54,369	$ 60,027	$ 3,885
Investing activities	(43,499)	(133,511)	(32,055)
Financing activities	(6,041)	15,664	1,176
Net Cash Flows	$ 4,829	$ (57,820)	$ (26,994)

Operating Activities:

Net cash provided by operating activities for 2007 primarily resulted from our receipt of $50.0 million in milestone payments from Shire, our receipt of $28.8 million in cash distributions from Novogyne, and our receipt of $5.9 million in connection with the amphetamine transdermal system agreement with Shire. These amounts were partially offset by changes in working capital due to the timing of certain payments, including $23.7 million in tax payments, $3.0 million related to insurance and $3.1 million in compensation and related liabilities.

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

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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.

Investing Activities:

Net cash used in investing activities for 2007 was primarily attributable to $130.4 million in acquisition costs related to the acquisition of JDS, net of cash acquired, and $2.8 million in equipment purchases to support operations and expansion of facilities, partially offset by $90.1 million of proceeds from net distributions of short-term investments primarily used to fund the JDS acquisition.

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.

Financing Activities:

Net cash used in financing activities for 2007 was primarily attributable to the open-market purchase of $5.1 million of shares of our common stock under the stock repurchase program established in the third quarter of 2007 and the payment of a $3.7 million long-term obligation assumed as part of the acquisition of JDS. These payments were offset by $2.5 million received in connection with the issuance of common stock resulting from the exercise of stock options. In addition, 2007 benefited from $0.4 million in excess tax benefit from the exercise of stock options.

Net cash provided by financing activities in 2006 and 2005 was attributable to $13.2 million and $1.3 million, respectively, received as the exercise price paid by the option holders in connection with their exercises of stock options. In addition, 2006 benefited from $2.6 million in excess tax benefit from the exercise of stock options, which prior to the adoption of SFAS No. 123(R) was reported in operating activities.

Short-Term and Long-Term Liquidity:

Our principal sources of short-term liquidity are existing cash and short-term investments, cash generated from product sales, milestones, fees and royalties under development and license agreements and distributions from Novogyne.

Our short-term cash flow is significantly dependent on distributions from Novogyne and sales, royalties and license fees associated with our products. Any material decrease in sales of those products by us or our licensees, a material decline in the HT market, the introduction of a generic version of Vivelle-Dot, material increase in operating expenses, or the inability or failure of Novogyne to pay distributions, would have a material adverse effect on our short-term cash flow and

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require us to rely on our existing cash balances, investments, equity or debt offerings or on borrowings to support our operations and business. 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 liquidity is also dependent on our receipt from Shire of the third and final $25 million milestone payment related to our Daytrana patch. To date, we have received $125 million of the possible $150 million related to the Shire license of Daytrana. We cannot assure if or when we will receive the third milestone (triggered upon Shire s achievement of $75.0 million in annual net sales of Daytrana). For the year ended December 31, 2007, we paid an aggregate $23.7 million in taxes, of which approximately $18.0 million relates to Daytrana milestones received to date. The majority of the income taxes related to the first and second sales milestones are expected to be paid in 2008 and into early 2009.

We expect to increase our research and development expense significantly beginning in 2008 to fund our projects under development, including those for Noven Therapeutics. We expect to fund the additional research and development expenses from our operating cash flows, existing cash and short-term investments as well as the sources of funds described herein. Given our planned expenditures for research and development, sales and marketing and other operating items in 2008, we generally expect that our cash, cash equivalents and other investments at year-end 2008 will decrease from year-end 2007 levels.

Our liquidity may be significantly harmed if we are unable to adequately resolve the issues raised by the FDA in the warning letter we received in January 2008. No assurance can be given that Noven s response to the warning letter will be acceptable to the FDA or satisfactorily address the FDA s concerns. Failure to take effective corrective actions can result in FDA enforcement action such as monetary fines, product recalls, injunctions, seizures, suspension of production or withdrawal of product approval. Any enforcement action by the FDA would have a material adverse effect on Noven, including the potential loss of Daytrana sales, the potential loss of sales of other products, the potential inability to achieve the remaining Daytrana sales milestone, the potential for litigation related to this matter, harm to our reputation and various costs associated with the foregoing.

We have invested a significant portion of our cash in auction rate securities, which subjects us to the liquidity risk described in Part II Item 7A Quantitative and Qualitative Disclosures About Market Risk. Subsequent to December 31, 2007, $17.6 million of auction rate securities were liquidated through the auction process. As of March 24, 2008 $37.4 million of these investments were rolled over following failed auctions. As a result of failed auctions, the auction rate securities could not be liquidated and pay interest at a maximum rate as defined by the governing documents or indenture. Due to uncertainty about when we will be able to liquidate these investments, we have reclassified all auction rate securities which have not been sold subsequent to December 31, 2007, as non-current assets, as the availability of such funds is subject to market conditions that may continue for an indeterminable period of time.

We paid approximately $125.0 million in cash to acquire JDS and incurred approximately $5.4 million in transaction-related costs. In addition, we assumed approximately $16.1 million of accrued expenses and other current liabilities and assumed certain contractual arrangements whereby we may be required to pay to third parties up to $23.5 million in product development and sales milestones that could become due over the next five years. We funded the purchase price and related transaction expenses from our sale of short-term investments.

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Our liquidity for the year ended December 31, 2007 benefited from $2.5 million received as the exercise price paid by option holders in connection with their exercises of employee stock options. We expect this amount to fluctuate from period to period depending on the performance of Noven s common stock and equity award exercises. Beginning in 2006, we began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options. These types of awards do not provide cash to us upon their exercise. Accordingly, we expect that funds received from option exercises will decrease as a source of liquidity over time.

In 2007 we used $5.1 million to repurchase a total of 322,345 shares of our common stock under our stock repurchase program.

We currently have no long-term debt. To the extent the sources of liquidity described herein are insufficient to fund our operations, including our anticipated increased research and development expenses, we would expect to undertake a debt and/or equity financing as a source of liquidity. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory financing, we may be required to delay or reduce our proposed expenditures, including expenditures for research and development, plant and equipment and strategic acquisitions. Furthermore, debt financing would likely require us 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.

Our strategic plan includes the acquisition of one or more products, technologies or businesses that we believe may be complementary to our business. While our existing cash and investments may fund a portion of a strategic acquisition, we expect that we will be required to seek debt and/or equity financing to complete such an acquisition. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms.

Capital expenditures totaled $2.8 million for 2007. We expect to fund our foreseeable capital expenditures from our operating cash flows, existing cash, short-term investments and debt. Although subject to the liquidity risk for auction rate securities discussed above, we believe that we have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements. To enhance our liquidity position, we are currently seeking a credit facility, although we cannot assure that we will successfully obtain a credit facility on favorable terms or at all.

If our transdermal 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. To the extent available, we may use funds generated through sales of products under development and payments received pursuant to development and licensing arrangements. If such funds are insufficient, we may rely on debt and/or equity financing to fund such expansion. 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 will 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 cash generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that

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could impact our ability to develop or acquire and launch additional commercially-viable products are discussed in Part I Item 1A Risk Factors of this Form 10-K.

For the years ended December 31, 2007, 2006 and 2005, our equity in earnings of Novogyne, the recognition of deferred license revenue and IPR&D expense (all of which are non-cash items) contributed significantly to our income (loss) before income taxes. Accordingly, our net income (loss) may not be reflective of our cash flow in any given period.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Aggregate Contractual Obligations

The table below lists our significant contractual obligations as of December 31, 2007 (amounts are in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations[1]	$ 8,028	$ 1,432	$ 2,784	$ 1,925	$ 1,887
Capital Lease Obligation[2]	404	200	179	16	9
Deferred Compensation Obligation	580	11	459		110
Long-Term Obligations[3]	11,500	3,250	3,250	5,000	
Purchase Obligations[4]	18,433	18,378	55		
Unrecognized Tax Benefits	1,371	237	303	484	347
Total	$ 40,316	$ 23,508	$ 7,030	$ 7,425	$ 2,353

1 In the ordinary course of business, we enter into operating leases for machinery, equipment, warehouse and office space. Total lease expense for operating leases was $1.5 million, $1.2 million and $1.1 million for the years ended December 31, 2007, 2006 and 2005, respectively.

2

During 2007 and 2006, Noven entered into capital lease obligations totaling $0.1 million and $0.4 million for new equipment, respectively, of which $0.4 million (including interest) remains outstanding as of December 31, 2007.

3 As of December 31, 2007, Noven Therapeutics was responsible for $23.5 million in contingent milestones, which may be payable over the next three to five years. As of December 31, 2007, $11.5 million of these milestones were reflected as liabilities in Noven s consolidated balance sheet. See Note 5 Contract and License Agreements for additional information.

4 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.

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Outlook

A summary of our current financial guidance is provided below. Our guidance includes certain items related to the impact on our financial results of our acquisition of JDS Pharmaceuticals (now known as Noven Therapeutics), which we acquired in August, 2007. This financial guidance supersedes all financial guidance that we may have previously provided; any financial guidance previously provided in areas not addressed below, whether in prior filings with the Securities and Exchange Commission, press releases, public conference calls or otherwise, is no longer current and is hereby withdrawn. The forward-looking information contained in this section is based on our current assumptions and expectations, many of which are beyond our control. In particular, for purposes of this guidance we have assumed that, during 2008, 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/withdrawals, or new study results);

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

adverse actions by the FDA in connection with the January 2008 warning letter or otherwise;

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, including additional risks and uncertainties related to Noven Therapeutics, readers should carefully consider the risks, uncertainties and cautionary factors discussed in Part I Item 1A Risk Factors of this Form 10-K, as well as other reports filed from time to time with the Securities and Exchange Commission. Net revenues, gross margin, expenses, net income (loss) and other aspects of our financial results can vary substantially from quarter-to-quarter based upon a number of factors, including the timing of product orders by our licensees, the timing of release of manufactured product following quality control and quality assurance measures undertaken by Noven and/or its customers, the availability of raw materials, the timing of commencement of clinical studies, and other factors.

Net Revenues. We expect total net revenues for full year 2008 to be in the $100 million to $105 million range, reflecting: (i) a full year of sales of Pexeva® and Lithobid®; (ii) recognition of nominal revenues associated with the expected launch of Stavzor in the second half of 2008, reflecting the fact that, pursuant to applicable accounting rules, we expect to recognize Stavzor revenues based on prescriptions filled as opposed to upon shipment to trade customers; (iii) an approximate 10% increase in our Daytrana net sales to Shire compared to 2007; (iv) higher license and contract revenues compared to 2007 due to the full-year amortization of Daytrana sales milestones received in 2007; and (v) aggregate HT product sales by Noven for sales in the U.S. and international markets consistent with 2007 levels.

Gross Margin. We expect our overall gross margin, as a percentage of product sales, to be in the 40% range for full year 2008. Among other factors influencing our gross margin on transdermal manufacturing operations, we expect to incur increased quality assurance costs related to our continued efforts to address the issues raised by the FDA in the July 2007 Form 483 and January 2008 warning letter. A significant portion of these costs will be allocated to

Daytrana , which will negatively affect the gross margin on sales of this product in 2008. We expect our cost of goods in

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2008 to include approximately $3.5 million in amortization associated with Noven Therapeutics commercialized products, which amount may vary depending on sales forecasts and other factors.

Research and Development Expense. We expect our consolidated research and development expense for full year 2008 to be in the mid- $20 million range. Estimates of research and development expenses for future periods are subject to substantial adjustment as each product advances through various stages of development.

Selling, General and Administrative Expense. We expect our consolidated selling, general and administrative expense for full year 2008 to be in the upper $50 million range, including selling and promotional expenses in support of Noven Therapeutics existing products and the expected commercial launch of Stavzor .

Equity in Earnings of Novogyne. We expect our equity in earnings of Novogyne to increase in the 10% range in 2008 compared to 2007.

Interest Income. We expect our interest income to decrease in 2008 compared to 2007, primarily reflecting lower cash and investment balances following payment of the JDS acquisition purchase price in August 2007.

Critical Accounting Estimates

Our discussion and analysis of our consolidated financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated 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 as well as estimates related to product returns and sales allowances, the fair value of stock-based compensation granted to employees and outside directors, as well as the net realizable value of our inventories and our deferred tax asset and our effective tax rate and the recoverability and fair value of our intangible assets and goodwill. 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:

License Revenues, Multiple Element Arrangements and Contract Revenues

License revenues include up-front, milestone and similar payments under license agreements. These agreements may contain multiple deliverables, such as product development, technology licenses, contract research and development, and the manufacturing and supply of products.

We recognize license revenue in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin Topic 13, Revenue Recognition, and Emerging Issues Task Force

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(EITF) Issue 00-21, Revenue Arrangements with Multiple Deliverables, as applicable. Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has standalone value to the customer, and whether there is objective, reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values or using the residual method, as appropriate, and the applicable revenue recognition criteria are identified and applied to each of the units. If multiple deliverables do not meet the separation criteria of EITF Issue 00-21, they are accounted for as a single unit of accounting and management applies a revenue recognition method that best reflects the economic substance of the transaction. In selecting the appropriate method to apply, management considers the specific facts and circumstances of each transaction, giving particular emphasis to the manner in which the customer receives the benefit of the transaction.

In general, revenues from nonrefundable, up-front license fees received prior to or upon product approval are deferred until the revenue recognition criteria have been satisfied and the customer begins to derive the value and benefits from the use of, or access to, the license. Our obligations generally are completed upon achieving regulatory approval of the licensed products, upon delivery of our development work, or when we have delivered a commercially viable license to our technology. In multiple element arrangements where research and development work does not meet the separation criteria of EITF Issue 00-21 (as has typically been the case for our agreements), our policy is to recognize such revenues over the product s estimated life cycle. Our arrangements generally culminate in the delivery to the licensee of technology licenses to market and sell products we have developed in a licensed territory. Consequently, applying the guidance of EITF Issue 00-21, we have determined that these deliverables should be accounted for as a single unit of accounting. Furthermore, we have concluded that the most appropriate revenue attribution method is to defer license revenues and recognize them over the products estimated life cycles, as the customer derives the value from the use of, or access to, the license. When we are unable to estimate the pattern of the expected economic benefits, the deferred revenues are amortized on a systematic and rational (straight-line) basis over the product s estimated life cycle.

We evaluate the facts and circumstances surrounding achievement of nonrefundable sales milestones to ensure that revenue recognition represents the substance of the transaction. Substantive sales milestones are recognized as revenue when achieved based on the substance of the underlying transactions, when we have fulfilled all of our obligations relative to the milestone payments. Non-substantive sales milestones are not recognized immediately as revenue when achieved, but are deferred and recognized as revenues over time in a manner that is consistent with the underlying facts and circumstances.

In determining the estimated life cycles over which to recognize license revenues, we consider the remaining life of proprietary protection and the economic lives of competing products in the specific or similar therapeutic categories. We believe the estimated product life cycle (the estimated economic life) generally ends when prescription trends decline to less than 20% of the product s peak prescriptions, which can be impacted by introductions of competing branded products, generic competition, and/or changes/improvements in forms of treatment therapy.

In the event that we receive a nonrefundable payment for a product that does not ultimately receive regulatory approval, the payment is recognized as revenue when all efforts cease, the project has been discontinued and we have no further obligation relating to the product.

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In 2003 and 2004, we entered into two sets of collaboration agreements with Shire:

A 2003 agreement consisting primarily of the transfer to Shire of a license to market and sell Daytrana and a manufacturing and supply agreement under which we agreed to supply product to Shire; and

A 2004 agreement, as amended, to develop an amphetamine-based transdermal patch to treat ADHD and a related license agreement.

Key elements of these agreements are described in Note 5 Contract and License Agreements to the consolidated financial statements. Our revenue recognition related to these agreements is described below.

Shire Collaboration Daytrana

Under the Shire Daytrana collaboration arrangement, we determined that there were three deliverables: (1) a license; (2) a research and development arrangement; and (3) a manufacturing and supply agreement.

The license and research and development deliverables in this agreement did not meet the criteria for separation under EITF 00-21; therefore, they were combined and accounted for as a single unit of accounting. we concluded that the manufacturing and supply agreement was at fair value based on our experience with similar arrangements; as a result, we accounted for it separately from the single unit of accounting (license and research and development deliverable). Accordingly, all milestone payments (including the up-front payment, FDA approval payment and subsequent sales milestones) were allocated to the single unit of accounting. In accordance with our policy, we began to recognize revenue for the single unit of accounting when the revenue recognition criteria related to all deliverables had been satisfied. Specifically, this occurred upon FDA approval of Daytrana in April 2006, at which time all of our obligations were satisfied, Shire had a commercially viable license and Shire began realizing the value of the deliverable.

Since this agreement provides for multiple payment streams, we recognize revenue as a single unit of accounting using a single attribution model for the license and research and development deliverables, whereby all milestone payments are recognized using the straight-line method over the estimated life cycle of Daytrana (estimated to be seven years), as Shire derives the value from the use of, or access to, the license.

Shire Collaboration Amphetamine

In connection with the 2004 amphetamine collaboration, Shire paid us a nonrefundable payment of $1.0 million in August 2006, in exchange for the option to purchase, for an additional $5.9 million, the exclusive developmental rights to the product. The agreement, as amended, provided that we would perform certain early-stage development activities. We completed a Phase 1 clinical study for the product in March 2007. In June 2007, Shire exercised its option to acquire the exclusive development rights to the product and we received the $5.9 million option payment.

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Simultaneous with the $5.9 million payment, we agreed to modify the patch formulation in order to align the amphetamine patch with Shire s future direction in the ADHD market. Shire has agreed to pay us for our development efforts in this regard. Applying the guidance in EITF Issue 00-21, the development agreement for the new formulation is, in essence, a modification and continuation of the original development agreement and, as a result, the total $6.9 million arrangement consideration is considered a single unit of accounting. This $6.9 million arrangement consideration was included in deferred license and contract revenues on our consolidated balance sheet as of December 31, 2007.

We have agreed to deliver a combination of development work and a license to market and sell this new product. Applying the guidance of EITF Issue 00-21, we concluded that the license does not have standalone value to Shire absent completion of our development efforts. Thus, the deliverables have been combined into a single unit of accounting. Revenue recognition will commence when the license has been delivered, we have fulfilled our obligations and Shire begins realizing the value of the license deliverable related to this product. The $6.9 million and any additional consideration will be amortized on a systematic and rational (straight-line) basis over the product s estimated life cycle, including Shire s development period, as our performance and obligations will be complete once delivery of the license takes place.

Contract Revenues

Contract revenues consist of contract payments related to research and development projects performed for third parties where we have determined that such projects are separate units of accounting. The work we perform may include feasibility studies to determine if a specific drug can be delivered transdermally, 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.

We recognize revenue from nonrefundable up-front payments based on the proportional performance method as we perform research and development work. We recognize additional payments received upon completion of additional phases and milestone payments when the specified performance criteria are achieved under the milestone method as long as such milestones are substantive. We record any difference between the amount of the payments received and the amount recognized as deferred license and contract revenues on our consolidated balance sheet until such amount is earned.

Revenue Recognition Novogyne

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

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allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenues.

The following table describes the activity for the revenue deduction accruals by major category for Novogyne (in which we hold a 49% investment and account for using the equity method) for the year ended December 31, 2007 (amounts in thousands):

	January 1, 2007	Payments	Income Statement Charge (Reversal) Adjustments of prior years	Current Year	December 31, 2007
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 472	$ (1,213)	$ 30	$ 1,607	$ 896
Managed health care rebates	4,691	(11,768)	477	12,749	6,149
Chargebacks, including hospital chargebacks	98	(1,285)		1,298	111
Cash discounts, direct customer discounts & other discounts	671	(5,368)		5,751	1,054
Sales returns allowances	7,938	(3,349)	(1,925)	3,372	6,036
Total	$ 13,870	$ (22,983)	$ (1,418)	$ 24,777	$ 14,246

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

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

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

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

Prior to 2006, the products also participated in prescription drug savings programs that offer savings to patients that are eligible participants under United States Medicare programs. These savings vary based on a patient s current drug coverage and personal income levels. Provisions for the obligations under these programs are based on historical experience, trend analysis and current program terms.

On January 1, 2006, an additional prescription drug benefit was added to the United States Medicare program 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.

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.

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

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sold and the latest date on which a return could occur. Novogyne believes this is a reasonable basis on which to estimate returns exposure and incorporates the key factors that contribute to returns. In addition, Novogyne establishes sales returns allowances for product that has been recalled or that it believes is probable of being recalled. The methodology used to estimate product returns associated with recalls is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Novogyne s product supply policy is to maintain inventories on a consistent level from year to year based on the pattern of consumption. Wholesaler inventory levels are monitored monthly based on gross sales volume, prescription volumes based on third party data and information received from the key wholesalers. Based on this information, the inventories on hand at wholesalers and other distribution channels were estimated to be approximately one month at December 31, 2007 and 2006. 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.

Revenue Recognition Noven Therapeutics

Revenues at Noven Therapeutics are recognized when all the risks and rewards of ownership have transferred to the customer, which occurs at the time of delivery. 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.

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The following table describes the activity for the revenue deduction accruals by major category for the period commencing with the acquisition of JDS (August 14, 2007) and ending December 31, 2007 (amounts in thousands):

	August 14, 2007	Payments	Income Statement Charge	December 31, 2007
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 3,792	$ (3,016)	$ 3,289	$ 4,065
Chargebacks, including hospital chargebacks	276	(488)	351	139
Cash discounts	92	(318)	285	59
Other discounts	292	(297)	775	770
Sales returns allowances	1,577	(368)	666	1,875
Total	$ 6,029	$ (4,487)	$ 5,366	$ 6,908

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 major wholesale customers, historical information and other analysis. Our management believes that it is able to reasonably estimate these sales deductions.

The revenue deductions for Noven Therapeutics and how we estimate the related accruals, are substantially similar to the revenue deductions at Novogyne, with the following exceptions:

Noven Therapeutics policy is that generally no product will be shipped to customers with less than twelve months of remaining shelf-life and generally returns due to expiration will be accepted within twelve months after the product has expired.

Noven Therapeutics 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 key wholesalers. Based on this information, the inventories on hand at wholesalers and other distribution channels are estimated to be approximately one month at December 31, 2007 for Pexeva® and Lithobid® products. We believe the third party data sources are sufficiently reliable; however, its accuracy cannot be independently verified.

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Intangible Assets and Goodwill

We account for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business based on estimates of their respective fair values. Amounts allocated to acquired in-process research and development are expensed at the date of acquisition. Intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The purchase price allocation for our Noven Therapeutics acquisition was substantially complete as of December 31, 2007. We are in the process of finalizing the determination of certain amounts that were subject to post closing true ups and adjustments. However, adjustments to the purchase price resulting from such items are not expected to be material.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives and methods used for amortization, can materially impact our results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. This process requires us to make estimates with respect to future sales volumes, pricing, new product launches, anticipated product costs and overall market conditions. Because these estimates influence the values assigned the various assets acquired, these estimates are considered to be critical accounting estimates. In connection with our acquisition of JDS, in addition to the value of acquired tangible assets and assumed liabilities, we recorded on our balance sheet $38.5 million of identifiable intangible assets, $14.7 million of goodwill, and $11.5 million of liabilities for contingent payments we expect to make related to the achievement of sales milestones for acquired products. Additionally, our cash flow estimates resulted in allocating $100.2 million of the purchase price to IPR&D, which was immediately charged to operations. Our forecast of future cash flows associated with IPR&D required various assumptions to be made including:

- revenues that are likely to result from the approved products or IPR&D projects, including estimated number of units to be sold, estimated selling prices, estimated market penetration, estimated market share, year-over-year growth rates over the product life cycles and estimated sales allowances;
- contract and license revenues generated by approved products or IPR&D projects;
- cost of sales for the potential products using historical data, industry data or other sources of market data;
- sales and marketing expenses using historical data, industry data or other sources of market data;
- general and administrative expenses;
- research and development expenses; and
- future equity in earnings of Novogyne.

Additional information about assumptions and other considerations related to the valuation of IPR&D can be found in the notes to our consolidated financial statements included in this Form 10-K.

Our goodwill is assigned to our Noven Therapeutics reporting segment. Goodwill is reviewed annually for impairment in the fourth quarter or more frequently, when events or other

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changes in circumstances indicate that the carrying amount of the goodwill may not be recoverable. If we determine at the date of the evaluation that the fair value of the reporting segment is less than its carrying value, then we would allocate the fair value of the segment to all of the assets and liabilities of the reporting segment in a manner similar to the allocation of purchase price in a business combination. A goodwill impairment would be recognized to the extent that the carrying value of goodwill exceeds the fair value not allocated to identifiable assets. In accordance with SFAS No. 141, our finite-lived intangible assets are evaluated for impairment whenever events or circumstances indicate that the carrying amounts may not be recoverable. We would recognize an impairment to the extent that the carrying value of a finite-lived intangible exceeds its fair value.

As of December 31, 2007, we determined that no impairment of goodwill or intangible assets existed. We will continue to assess the carrying value of goodwill and intangible assets in accordance with applicable accounting guidance.

Income Taxes

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. Our effective tax rate for 2007 was 35%, while our effective tax rate for 2006 and 2005 was 33% and 35%, respectively. If our effective tax rate differed from our estimate our results would vary.

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 due to the JDS acquisition increased to $65.7 million as of December 31, 2007 primarily due to the immediate charge to operations of IPR&D totaling $100.2 million which is deductible for tax purposes over 15 years. Estimates of future taxable income require us to make significant estimates that involve subjective and often complex judgments, the most significant of which relate to future cash flows of approved products and products in IPR&D.

Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics files separate state income tax returns in states where Noven Therapeutics has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. We expect that Noven Therapeutics will incur taxable state losses in the next few years due to future expected clinical trial expenditures related to product development. These expected taxable losses create negative evidence indicating the need for a valuation allowance at December 31, 2007. We recorded a valuation allowance of $3.2 million during the quarter ended September 30, 2007, due to uncertainties in realizing these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future Noven Therapeutics profitability that these state deferred tax assets are more likely

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than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

Accounting for Uncertainty in Income Taxes

On January 1, 2007, we adopted the provisions of and began accounting for uncertainty in income taxes in accordance with FIN 48. This interpretation requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. Under FIN 48 an enterprise cannot recognize a tax benefit for a tax position that is not likely to be sustained. The application of income tax law is inherently complex. Laws and regulations in this area are voluminous and are often ambiguous. As such, we are required to make many subjective assumptions and judgments regarding our income tax exposures. Interpretations and guidance surrounding income tax laws and regulations change over time. As a result, changes in our subjective assumptions, estimates and judgments can materially affect amounts recognized in our financial statements. See Note 14 to the consolidated financial statements, Income Taxes for additional information on our uncertain tax positions.

Stock-Based Compensation

On January 1, 2006, we adopted SFAS No. 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 No. 123(R) was $5.4 million and $3.3 million in 2007 and 2006, respectively.

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 and SSARs granted by taking the average of the vesting term and the contractual term of the option or SSAR, 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 or SSAR. 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 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 stock option and SSAR 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

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in the future. Stock options or SSARs may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, values may be realized from these instruments that are significantly higher than the fair values originally estimated on the grant dates, 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 $24.0 million in 2007, include 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 $12.1 million and $8.7 million as of December 31, 2007 and 2006, 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.

Novogyne Intangible Asset

As of December 31, 2007, Novogyne had a long-term intangible asset of $20.1 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 SFAS No. 144, Accounting for the Impairment of Disposal of Long-Lived Assets (SFAS No. 144), the CombiPatch® marketing rights are assessed for impairments whenever events or changes in

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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 reduce 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 condition and/or results of operations.

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 significant estimates, 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 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 $9.0 million as of December 31, 2007 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 $6.8 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. 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 cannot 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

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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, 2007.

New Accounting Standards

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin (ARB) No. 51 . SFAS No. 160 establishes accounting and reporting standards for the noncontrolling interest (minority interest) in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 amends certain of ARB 51 s consolidation procedures to conform them to the requirements of SFAS No. 141(R), Business Combinations , which was issued at the same time as SFAS No. 160. This new statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008 (that is, January 1, 2009, for entities with calendar year-ends). Earlier adoption is prohibited. SFAS No. 160 will be applied prospectively as of the beginning of the fiscal year in which this Statement is initially applied, except for the presentation and disclosure requirements, which will be applied retrospectively for all periods presented. We are currently assessing the impact of adopting SFAS No. 160 and the impact it may have on our consolidated results of operations, financial condition and cash flows.

In December 2007, the FASB revised SFAS No. 141, Business Combinations (SFAS 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer: (i) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; (ii) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and (iii) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) applies to all transactions or other events in which an entity (the acquirer) obtains control of one or more businesses (the acquiree), including those sometimes referred to as true mergers or mergers of equals and combinations achieved without the transfer of consideration, for example, by contract alone or through the lapse of minority veto rights. SFAS No. 141(R) does not apply to: (i) the formation of a joint venture; (ii) the acquisition of an asset or a group of assets that does not constitute a business; (iii) a combination between entities or businesses under common control; or (iv) a combination between not-for-profit organizations or the acquisition of a for-profit business by a not-for-profit organization. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply SFAS No. 141 (R) before that date. We are currently assessing the impact of adopting SFAS No. 141 (R) and the impact it may have on our consolidated results of operations, financial condition and cash flows.

In December 2007, the FASB s Emerging Issue Task Force (EITF) reached a consensus on EITF Issue No. 07-01, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property (EITF 07-01). EITF 07-01 discusses the appropriate income statement presentation and classification for the activities and payments between the participants in arrangements related to the development and commercialization of intellectual property. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. The sufficiency of disclosure related to these arrangements is also specified. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. We are

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currently assessing the impact of adopting EITF 07-01 and the impact it may have on our consolidated results of operations, financial condition and cash flows.

In June 2007, the EITF issued EITF Issue No. 07-03, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-03). This EITF requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. Entities should continue to evaluate whether they expect the goods to be delivered or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. We are currently assessing the impact of adopting EITF 07-03 and the impact it may have on our consolidated results of operations, financial condition and cash flows.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. This standard defines fair value, establishes a framework for measuring fair value in U.S. GAAP, and expands disclosure about fair value measurements. This standard applies under other accounting pronouncements that require or permit fair value measurements, but does not require any new fair value measurements. In February 2008 the FASB issued FASB Staff Position (FSP) 157-2 Effective Date of FASB Statement No. 157 . Under FSP 157-2, the provisions of SFAS No. 157 will be adopted for financial instruments in 2008 and, when required, for nonfinancial assets and nonfinancial liabilities in 2009 (except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis). Adoption of SFAS No. 157 is not expected to materially affect our consolidated financial statements. However, as a result of illiquid conditions in the market for auction rate securities beginning in February 2008, we may be required to employ inputs other than quoted prices in active markets for identical securities in order to value our investments. SFAS No. 157 would require disclosure about the inputs used to determine the fair value of our investments.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of SFAS No. 115 . This Statement permits entities to choose to measure many financial instruments and certain other items at fair value and applies to all entities. Most of the provisions of this Statement apply only to entities that elect the fair value option. However, the amendment to SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently assessing the impact of adopting SFAS No. 159 and the impact it may have on our consolidated results of operations, financial condition and cash flows.

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

At March 24, 2008, we held approximately $37.4 million in auction rate securities. Auction rate securities are floating rate debt securities with long-term nominal maturities, the interest rates of which are reset periodically (typically every 7 to 35 days) through a Dutch auction process. These periodic auctions have historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then-existing market rates or to liquidate their holdings by selling their securities at par value. In recent weeks as part of the ongoing credit market crisis, several auction

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rate securities from various issuers have failed to receive sufficient order interest from potential investors to clear successfully, resulting in an auction failure. Historically, when investor demand was insufficient, the banks running the auctions would step in and purchase the remaining securities to prevent an auction failure. Recently, however, the banks have been allowing these auctions to fail.

During the period from February 14, 2008 to March 24, 2008, auctions failed for approximately $33.4 million of auction rate securities still owned by us at March 24, 2008. As a result, the securities related to the failed auctions could not be liquidated and pay interest at a maximum rate allowed in the governing documents or indenture. We cannot predict when the liquidity of these securities will improve. Accordingly, as of December 31, 2007, we classified all of our auction rate securities as non-current ($32.8 million), with the exception of $17.6 million of securities that we liquidated subsequent to December 31, 2007 and a $4.0 million variable rate demand note supported by an irrevocable direct-pay letter of credit issued by a bank. Our liquidity will be adversely affected to the extent that auctions for our auction rate securities experience further failures. To enhance our liquidity position, we are currently seeking a credit facility, although we cannot assure that we will successfully obtain a credit facility on favorable terms or at all.

As of March 24, 2008, the auction rate securities that we hold are collateralized primarily by tax-exempt municipal bonds, and to a lesser extent, guaranteed student loans. We do not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. We believe our auction rate securities are of high credit quality, as approximately 75% of the investments carry an AA or AAA credit rating, and all are investment grade. We continue to monitor the market for auction rate securities and consider its impact on the fair market value of our investments. If the fair value of the investments were to decline, management would be required to evaluate whether such decline is other than temporary in accordance with SFAS No. 115. The amount of impairment which is determined to be temporary would be included in stockholders equity as a component of other comprehensive income or loss. The amount of any such impairment loss which is determined to be other than temporary would be immediately recorded in the consolidated statements of operations. Such a non-cash impairment charge could materially and adversely affect our consolidated financial condition and results of operations.

Item 8. Consolidated Financial Statements and Supplementary Data.

See Index to Consolidated Financial Statements at page 113 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, our management evaluated, with the participation of our Interim Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 promulgated

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under the Securities Exchange Act of 1934 (the Exchange Act). Based upon that evaluation, our CEO and CFO concluded that, as of December 31, 2007, our disclosure controls and procedures were effective in ensuring that information relating to Noven, including its consolidated subsidiaries, required to be disclosed in reports that it files or submits under the Exchange Act was: (1) recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms; and (2) accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. 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 Interim Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all errors and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and Novogyne s financial, accounting, inventory, sales and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to our equity investment in Novogyne are necessarily more limited than those we maintain with respect to Noven.

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Changes in Internal Control over Financial Reporting

No changes were made in our internal control over financial reporting during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control 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.

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, 2007. 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, 2007, 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 internal control over financial reporting. This report appears on page 100.

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Scope of Management s Report on Internal Control over Financial Reporting

For purposes of management s evaluation of our internal control over financial reporting as of December 31, 2007, we have elected to exclude recently acquired Noven Therapeutics from the scope of management s assessment as permitted by guidance provided by the SEC. We acquired JDS on August 14, 2007 and renamed it Noven Therapeutics, which represented approximately 33% of our consolidated assets at December 31, 2007 and contributed approximately 11% of total revenues in 2007. The Noven Therapeutics business will be included in management s assessment of the effectiveness of our internal control over financial reporting in fiscal year 2008.

In addition, management s evaluation of Noven s internal control over financial reporting at December 31, 2007 does not include an evaluation of internal control over financial reporting for Novogyne. Under the Novogyne joint venture, Novartis is responsible for Novogyne s internal control over financial reporting as well as for the financial and accounting functions at Novogyne. Noven does not consolidate Novogyne for financial reporting purposes and is not required to assess Novogyne s internal control over financial reporting. (Noven does maintain certain controls over recording accounts related to its investment in Novogyne and its equity interest in Novogyne s earnings in Noven s consolidated financial statements, including reviewing Novogyne s audited financial statements and related notes, included elsewhere in this Form 10-K.) Failure by Novartis to properly maintain internal control over financial reporting for Novogyne could negatively affect the financial condition and results of operations of Novogyne and Noven. Equity in earnings of Novogyne totaled $35.9 million for the year ended December 31, 2007. Our investment in Novogyne totaled $24.3 million at December 31, 2007 and represented approximately 8% of total consolidated assets.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of Noven Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in *Management s Report on Internal Controls Over Financial Reporting,* management excluded from its assessment the internal control over financial reporting at Noven Therapeutics, LLC, which was acquired on August 14, 2007 and whose financial statements constitute 43% and 33% of net and total assets, respectively, 11% of revenues, and 156% of net loss of the consolidated financial statement amounts as of and for the year ended December 31, 2007. Accordingly, our audit did not include the internal control over financial reporting at Noven Therapeutics, LLC. 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, included in the accompanying *Management s Report on Internal Controls Over Financial Reporting*. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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 consolidated financial statements as of and for the year ended December 31, 2007 of the Company and our report dated March 31, 2008 expressed an unqualified opinion on those consolidated financial statements.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants
Miami, FL
March 31, 2008

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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, Item 4 hereof. All other information required by Item 10 is incorporated by reference to our Proxy Statement for our 2008 Annual Meeting of Stockholders.

Item 11. Executive Compensation.

The information required by Item 11 is incorporated by reference to our Proxy Statement for our 2008 Annual Meeting of Stockholders.

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

Equity Plan Compensation Information

The following table provides summary information concerning the equity awards under Noven s compensation plans (security and share amounts in thousands) as of December 31, 2007:

Plan Category	Number of Securities To Be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding Securities Reflected in First Column)
Equity Compensation Plans Approved by Security Holders	3,511	$ 16.83	1,196
Equity Compensation Plans Not Approved by Security Holders	23	12.58	
Total	3,534	$ 16.80	1,196

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Information Concerning Security Ownership

The information concerning security ownership of certain beneficial owners and management required by this Item 12 is incorporated by reference to our Proxy Statement for our 2008 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 2008 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 2008 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See Index to Financial Statements at page 113 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 consolidated financial statements or the notes thereto.

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(a)(3) Exhibits

Exhibit Number	Description	Method of Filing
3.1	Noven s Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 of Noven s Form 10-K for the year ended December 31, 1998 (File No. 0-17254).
3.2	Noven s Certificate of Amendment of Certificate of Incorporation dated June 5, 2001.	Incorporated by reference to Exhibit 3.1 of Noven s Form 10-Q for the quarter ended June 30, 2001 (File No. 0-17254).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of Noven Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.3 of Noven s Form 8-K, dated November 15, 2007 (File No. 0-17254).
3.4	Noven s Bylaws, as amended and restated as of November 14, 2007.	Incorporated by reference to Exhibit 3.2 of Noven s Form 8-K dated November 13, 2007 (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 9, 2007, for the Annual Meeting of Shareholders held on May 18, 2007.
10.2	Form of Employment Agreement (Change of Control), between Noven and each of Jeffrey F. Eisenberg, W. Neil Jones, Juan A. Mantelle and Michael D. Price.*	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).
10.3	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).

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Exhibit Number	Description	Method of Filing
10.4	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).
10.5	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).
10.6	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).
10.7	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).
10.8	Marketing and Promotional Services Agreement by and between Noven and Vivelle Ventures LLC dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.4 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.9	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).
10.10	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).
10.11	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).
10.12	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer, Inc. dated September 30, 1999 (with certain	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q

provisions omitted pursuant to Rule 24b-2).	for the quarter ended September 30, 1999 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.13	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).
10.14	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).
10.15	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).
10.16	Sublicense Agreement among Rorer Pharmaceutical Products, Inc., Rhône-Poulenc Rorer Inc., Aventis Pharmaceuticals Products Inc., Rhône-Poulenc Rorer International Holdings Inc., Novartis Pharma AG and Noven dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.3 of Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.17	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).
10.18	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).
10.19	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).
10.20	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).

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Exhibit Number	Description	Method of Filing
10.21	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 10.1 of Noven s Form 10-Q for the quarter ended March 31, 2003 (File No. 0-17254).
10.22	Toll Conversion and Supply Agreement among Shire US Inc., Shire Pharmaceuticals Group PLC and Noven, dated as of April 7, 2003 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the year ended March 31, 2003 (File No. 0-17254).
10.23	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).
10.24	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).
10.25	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 December 31, 2003 (File No. 0-17254).
10.26	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).
10.27	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).
10.28	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).

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Exhibit Number	Description	Method of Filing
10.29	Letter Agreement between Noven and Procter & 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).
10.30	Industrial Long-Term Lease, dated February 22, 2005, between Noven and Deerwood Commerce Center LLC.**	Incorporated by reference to Exhibit 10.37 of Noven s Form 10-K for the year ended December 31, 2004 (File No. 0-17254).
10.31	Noven Pharmaceuticals, Inc. Nonqualified Deferred Compensation Plan, as amended and restated on 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).
10.32	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).
10.33	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).
10.34	Agreement and Plan of Merger, dated as of July 9, 2007, by and among Noven Pharmaceuticals, Inc., Noven Acquisition, LLC, JDS Pharmaceuticals, LLC, and Satow Associates, LLC.**	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated July 10, 2007 (File No. 0-17254).
10.35	Letter Agreement between Shire US Inc. and Noven related to Development of Amphetamine Transdermal Delivery System, 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, 2007 (File No. 0-17254).
10.36	Amendment dated May 3, 2007, to Letter Agreement between Shire US Inc. and Noven related to Development of Amphetamine Transdermal Delivery System dated June 15, 2004 (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 June 30, 2007 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.37	Amendment dated June 4, 2007, to Letter Agreement between Shire US Inc. and Noven related to Development of Amphetamine Transdermal Delivery System dated June 15, 2004 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.3 of Noven s Form 10-Q for the quarter ended June 30, 2007 (File No. 0-17254).
10.38	Non-Competition Agreement between Noven Pharmaceuticals, Inc. and Phillip Satow, dated as of August 14, 2007.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated August 20, 2007 (File No. 0-17254).
10.39	Consulting Agreement between JDS Pharmaceuticals, LLC and Phillip Satow, dated as of August 14, 2007.*	Incorporated by reference to Exhibit 10.2 of Noven s Form 8-K dated August 20, 2007 (File No. 0-17254).
10.40	Asset Purchase Agreement by and between Synthon Pharmaceuticals, Inc. and JDS Pharmaceuticals, LLC dated October 17, 2005 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.3 of Noven s Form 10-Q for the quarter ended September 30, 2007 (File No. 0-17254).
10.41	Development, License and Supply Agreement by and between Banner Pharmacaps Inc. and JDS Pharmaceuticals, LLC dated April 26, 2007 (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 September 30, 2007 (File No. 0-17254).
10.42	Contract Manufacturing Agreement between OSG Norwich Pharmaceuticals, Inc. and JDS Pharmaceuticals, LLC dated November 1, 2005 (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 September 30, 2007 (File No. 0-17254).
10.43	Letter Agreement, dated November 13, 2007, between Diane M. Barrett and Noven Pharmaceuticals, Inc.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated November 15, 2007 (File No. 0-17254).
10.44	Separation Agreement between Robert C. Strauss and Noven, dated January 2, 2008.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated January 3, 2008 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.45	Form of Restricted Stock Unit Agreement*	Incorporated by reference to Exhibit 10.2 of Noven s Form 8-K dated January 3, 2008 (File No. 0-17254).
10.46	Letter Agreement between Jeffrey F. Eisenberg and Noven, dated January 2, 2008.*	Incorporated by reference to Exhibit 10.3 of Noven s Form 8-K dated January 3, 2008 (File No. 0-17254).
10.47	Restricted Stock Agreement between Jeffrey F. Eisenberg and Noven, dated January 2, 2008.*	Incorporated by reference to Exhibit 10.4 of Noven s Form 8-K dated January 3, 2008 (File No. 0-17254).
10.48	Manufacturing and Supply Agreement between ANI Pharmaceuticals, Inc. and Noven Therapeutics, LLC (f/k/a, JDS Pharmaceuticals, LLC) dated January 2, 2008 (with certain provisions omitted pursuant to Rule 24b-2).**	Filed herewith.
11	Computation of Earnings (Loss) 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 Jeffrey F. Eisenberg, Executive Vice President and Interim Chief Executive 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.
31.2	Certification of Michael D. Price, 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.

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Exhibit Number	Description	Method of Filing
32.1	Certification of Jeffrey F. Eisenberg, Executive Vice President and Interim Chief Executive Officer, 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 Michael D. Price, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.***	Furnished herewith.

* Compensation Plan or Agreement.

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

*** 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.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2008

NOVEN PHARMACEUTICALS, INC.

By: /s/ Jeffrey F. Eisenberg

Jeffrey F. Eisenberg
Executive Vice President and
Interim Chief Executive Officer

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/ Jeffrey F. Eisenberg Jeffrey F. Eisenberg Executive Vice President and Interim CEO	Principal Executive Officer	March 31, 2008
By: /s/ Michael D. Price Michael D. Price Vice President & Chief Financial Officer	Principal Financial and Accounting Officer	March 31, 2008
By: /s/ Wayne P. Yetter Wayne P. Yetter	Chairman of the Board and Director	March 31, 2008
By: /s/ Sidney Braginsky Sidney Braginsky	Director	March 31, 2008
By: /s/ John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 31, 2008
By: /s/ Donald A. Denkhaus Donald A. Denkhaus	Director	March 31, 2008
By: /s/ Pedro P. Granadillo Pedro P. Granadillo	Director	March 31, 2008
By: /s/ Phillip M. Satow	Director	March 31, 2008

	Phillip M. Satow		
By:	/s/ Robert G. Savage	Director	March 31, 2008
	Robert G. Savage		

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Noven Pharmaceuticals, Inc. and subsidiaries (Noven) as of December 31, 2007 and 2006, and the related consolidated statements of operations, change in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of Noven s management. Our responsibility is to express an opinion on the 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, 2007, 2006, and 2005. Noven s investment in Vivelle Ventures LLC of $24,310,000 and $23,296,000 at December 31, 2007 and 2006, respectively, and Noven s share of that joint venture s income of $35,850,000, $28,632,000, and $24,655,000 for the years ended December 31, 2007, 2006, and 2005, respectively, are included in the accompanying consolidated 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, is based solely on the report of the 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 consolidated financial statements present fairly, in all material respects, the financial position of Noven Pharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, Noven changed its 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), Noven s internal control over financial reporting as of December 31, 2007, 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 31, 2008 expressed an unqualified opinion on Noven s internal control over financial reporting based on our audit.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants
Miami, FL
March 31, 2008

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2007	2006
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,973	$ 9,144
Short-term investments available-for-sale, at fair value	21,565	144,455
Accounts receivable (less allowances of $252 at 2007 and $67 at 2006)	6,956	5,038
Milestone payment receivable Shire		25,000
Accounts receivable Novogyne, net	8,683	7,693
Inventories	12,136	8,651
Net deferred income tax asset, current portion	7,614	4,400
Prepaid income taxes	4,925	3,416
Prepaid and other current assets	5,251	2,410
	81,103	210,207
Non-current Assets:		
Property, plant and equipment, net	36,213	37,010
Investments in auction rate securities	32,835	
Investment in Novogyne	24,310	23,296
Net deferred income tax asset, non-current portion	58,053	8,308
Intangible assets, net	38,773	2,317
Goodwill	14,734	
Deposits and other non-current assets	677	227
	205,595	71,158
	$ 286,698	$ 281,365
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 8,399	$ 5,184
Accrued compensation and related liabilities	9,801	5,308
Other accrued liabilities	15,270	2,174
Current portion of long-term obligations	3,421	109
Deferred license and contract revenues current portion	20,188	16,611
	57,079	29,386
Non-current Liabilities:		
Long-term obligations, less current portion	8,438	279
Deferred license and contract revenues, non-current portion	85,056	74,188
Other non-current liabilities	1,831	837

	95,325	75,304
Total Liabilities	152,404	104,690
Commitments and Contingencies (Notes 5 and 17)		
Stockholders Equity:		
Preferred stock authorized 100,000 shares par value $.01 per share; no shares issued or outstanding		
Common stock authorized 80,000,000 shares, par value $.0001 per share; 24,881,867 issued at December 31, 2007; 24,661,169 issued and outstanding at December 31, 2006	2	2
Additional paid-in capital	118,561	109,912
Retained earnings	20,855	66,761
Treasury stock, at cost - 322,345 shares at December 31, 2007	(5,124)	
Common stock held in trust	(950)	(375)
Deferred compensation obligation	950	375
	134,294	176,675
	$ 286,698	$ 281,365

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

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Years Ended December 31,		
	2007	2006	2005
Revenues:			
Product revenues Novogyne:			
Product sales, net	$ 22,425	$ 19,714	$ 19,910
Royalties	7,458	6,845	6,444
Total net product revenues Novogyne	29,883	26,559	26,354
Product revenues, net third parties	35,553	21,767	14,097
Total net product revenues	65,436	48,326	40,451
License and contract revenues	17,725	12,363	12,081
Total net revenues	83,161	60,689	52,532
Costs and Expenses:			
Cost of products sold Novogyne	13,683	14,102	13,547
Cost of products sold third parties	27,334	22,406	20,500
Total cost of products sold	41,017	36,508	34,047
Acquired in-process research and development	100,150		
Research and development	13,978	11,454	13,215
Selling, general and administrative	39,571	21,701	16,915
Total costs and expenses	194,716	69,663	64,177
Loss from operations	(111,555)	(8,974)	(11,645)
Equity in earnings of Novogyne	35,850	28,632	24,655
Interest income, net	5,454	4,272	2,242
Income (loss) before income taxes	(70,251)	23,930	15,252
Provision (benefit) for income taxes	(24,875)	7,942	5,280
Net income (loss)	$ (45,376)	$ 15,988	$ 9,972

Basic earnings (loss) per share	$ (1.84)	$ 0.67	$ 0.42
Diluted earnings (loss) per share	$ (1.84)	$ 0.66	$ 0.42
Weighted average number of common shares outstanding:			
Basic	24,728	23,807	23,566
Diluted	24,728	24,252	23,981

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

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders Equity
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Treasury Stock	Other	Total
Balance at December 31, 2004	23,481	$ 2	$ 88,236	$ 40,801	$	$	$ 129,039
Issuance of shares pursuant to employee equity plan	136		1,290				1,290
Tax benefit from exercise of employee equity grants			281				281
Compensation expense related to equity grants			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	1,040		13,224				13,224
Stock-based compensation expense and issuance of shares to outside directors	4		3,286				3,286
Common stock held in trust	(21)					(375)	(375)
Deferred compensation obligation	21					375	375
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
Cumulative effect of the adoption of FIN 48 (Note 2)				(530)			(530)
Issuance of shares pursuant to employee equity plan	162		2,545				2,545
Issuance of SSARs pursuant to non-competition agreement			265				265
Stock-based compensation expense and issuance of shares to outside directors	59		5,381				5,381
Repurchase of shares pursuant to stock repurchase plan	(322)				(5,124)		(5,124)
Common stock held in trust	(27)					(575)	(575)
Deferred compensation obligation	27					575	575
Tax benefit from exercise of employee equity grants			458				458
Net loss				(45,376)			(45,376)
Balance at December 31, 2007	24,560	$ 2	$ 118,561	$ 20,855	$ (5,124)	$	$ 134,294

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

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(in thousands)

	Years ended December 31,		
	2007	2006	2005
Cash flows from operating activities:			
Net income (loss)	$ (45,376)	$ 15,988	$ 9,972
Adjustments to reconcile net income (loss) to net cash flows provided by operating activities:			
Depreciation, amortization and certain other noncash items	6,860	4,429	3,126
Stock based compensation expense	5,381	3,286	
Acquired in-process research and development expense	100,150		
Income tax benefits on exercise of stock options	458	3,556	281
Excess tax benefit from exercise of stock options	(370)	(2,590)	
Deferred income tax (benefit) expense	(52,601)	(335)	2,566
Recognition of deferred license and contract revenues	(17,725)	(12,363)	(12,081)
Equity in earnings of Novogyne	(35,850)	(28,632)	(24,655)
Distributions from Novogyne	28,844	26,368	26,187
Write-off of inventories deemed non-saleable			9,475
Changes in operating assets and liabilities, net of acquisition:			
Decrease (increase) in accounts receivable trade, net	2,928	(27,119)	2,476
(Increase) decrease in accounts receivable Novogyne, net	(990)	1,219	1,186
Decrease in milestone payment receivable Shire	25,000		
Increase in inventories	(1,230)	(790)	(1,348)
Decrease in prepaid income taxes	4,483	6,492	3,105
Increase in prepaid and other current assets	(2,731)	(1,053)	(119)
(Increase) decrease in deposits and other assets		(15)	3
Decrease in accounts payable and accrued expenses	(3,743)	(6,116)	(11,463)
Increase (decrease) in accrued compensation and related liabilities	3,121	(463)	9
Increase (decrease) in other accrued liabilities	4,716	(39)	(891)
Increase (decrease) in deferred license and contract revenues	32,125	78,012	1,933
Increase in other liabilities	874	178	
Amounts reimbursable to (recoverable from) Shire and offset against deferred license revenues related to Daytrana approval	45	14	(5,877)
Cash flows provided by operating activities	54,369	60,027	3,885
Cash flows from investing activities:			
Purchases of property, plant and equipment	(2,753)	(6,261)	(13,669)
Payments for intangible assets	(181)	(616)	(486)
Acquisition of JDS, net of cash acquired	(130,360)		
Purchase of company-owned life insurance	(260)	(185)	
Purchases of investments	(1,568,598)	(1,298,424)	(516,505)
Proceeds from sale of short-term investments	1,658,653	1,171,975	498,605
Cash flows used in investing activities	(43,499)	(133,511)	(32,055)

Cash flows from financing activities:			
Issuance of common stock from exercise of stock options	2,545	13,224	1,290
Repurchase of common stock	(5,124)		
Excess tax benefit from exercise of stock options	370	2,590	
Payments of long-term obligations	(3,832)	(150)	(114)
Cash flows (used in) provided by financing activities	(6,041)	15,664	1,176
Net increase (decrease) in cash and cash equivalents	4,829	(57,820)	(26,994)
Cash and cash equivalents, beginning of year	9,144	66,964	93,958
Cash and cash equivalents, end of year	$ 13,973	$ 9,144	$ 66,964

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

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS:

Since its incorporation in Delaware in 1987, Noven Pharmaceuticals, Inc. (Noven) has been primarily 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 product delivery systems marketed under the brand names Vivelle-Dot®, Vivelle® and CombiPatch®.

On August 14, 2007 (the Closing Date), Noven acquired JDS Pharmaceuticals, LLC (JDS), a privately-held specialty pharmaceutical company that currently markets two branded prescription psychiatry products through a targeted sales force and has a pipeline of products in development. The acquisition of JDS was accounted for using the purchase method of accounting and the results of operations of JDS have been included in Noven s consolidated results from the Closing Date through December 31, 2007 (see Note 4 Acquisition of JDS Pharmaceuticals, LLC). Effective January 8, 2008, JDS name was changed to Noven Therapeutics, LLC (Noven Therapeutics).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

BASIS OF CONSOLIDATION:

The consolidated financial statements include the accounts of Noven Pharmaceuticals, Inc. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. Noven accounts for its 49% investment in Novogyne using the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Consolidated 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.

SEGMENT INFORMATION:

With the addition of Noven Therapeutics, Noven s business is now comprised of two reportable segments: (i) Noven Transdermals , which currently consists of sales of transdermal products and the research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products; and (ii) Noven Therapeutics , which currently consists of development, marketing and sales of pharmaceutical products. As a result of the acquisition, Noven now presents segment disclosures in accordance with Statement of Financial Accounting Standards (SFAS) No. 131, Disclosures about Segments of an Enterprise and Related Information. See Note 15 Segment and Customer Data for Noven s segment reporting.

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USE OF ESTIMATES:

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated 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 values as earned; (b) estimating when the license period begins and determining the period of recognition over which revenues will be earned, e.g., 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; and (d) estimating sales allowances and returns; (ii) determining the useful lives and method used for amortizing intangible assets (iii) determination of the fair value of employee equity awards in order to determine compensation expense; (iv) the valuation of inventories and the allocation of overhead expenses; (v) whether or not to capitalize pre-launch inventories; (vi) the allocation of purchase price to acquired assets including identifiable intangibles and goodwill; (vii) determination of the economic lives of intangible assets; (viii) estimates of cash flows used to assess the recoverability and fair values of intangible assets and goodwill; and (ix) determination of the net realizable value of the net deferred tax asset, estimation of the effective tax rate and income and other tax accruals.

The most significant estimates made by the management of Novogyne impacting Noven s consolidated 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 (which impacts estimates in Noven s financial statements); and (iii) Novogyne s provisions for product liability claims and anticipated recovery of insurance related receivables.

CASH AND CASH EQUIVALENTS:

Cash and cash equivalents include 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, 2007 and 2006, 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 2005, Noven invested a portion of its cash in investments, consisting primarily of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are classified as available-for-sale under the provisions of SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities . In accordance with SFAS No. 115, these investments are reported in the consolidated balance sheets at fair value. Any

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unrealized gains and losses are included in comprehensive income (loss) as a separate component of stockholder s equity, net of applicable taxes.

At March 24, 2008, Noven held approximately $37.4 million in auction rate securities. Auction rate securities are floating rate debt securities with long-term nominal maturities, the interest rates of which are reset periodically (typically every seven to thirty-five days) through a Dutch auction process. These periodic auctions have historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then existing market rates or to liquidate their holdings by selling their securities at par value. Beginning in February 2008, as part of the ongoing credit market crisis, several auction rate securities from various issuers have failed to receive sufficient order interest from potential investors to clear successfully, resulting in auction failures. Historically, when investor demand was insufficient, the banks running the auctions would step in and purchase the remaining securities in order to prevent an auction failure. However, as of recently they have been allowing these auctions to fail.

Subsequent to year-end, approximately $17.6 million of auction rate securities owned by Noven as of December 31, 2007 were liquidated through the auction process. During the period from February 14, 2008 to March 24, 2008, auctions failed for approximately $33.4 million auction rate securities still owned by Noven at March 24, 2008. As a result, the securities related to the failed auctions now pay interest at a maximum rate allowed in the governing documents or indenture. Noven cannot predict when the liquidity of these securities will improve. Accordingly, as of December 31, 2007, Noven classified all its auction rate securities as non-current ($32.8 million), with the exception of $17.6 million of securities that were liquidated subsequent to December 31, 2007 and a $4.0 million variable rate demand note supported by an irrevocable direct-pay letter of credit issued by a bank.

Noven s auction rate security investments are collateralized primarily by tax-exempt municipal bonds, and to a lesser extent, guaranteed student loans. Noven does not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. Approximately 75% of the investments carry an AA or AAA credit rating and all are investment grade. As of December 31, 2007, the fair value of Noven s securities approximated their par value. Prior to February 2008, each of the auction rate issues owned by Noven experienced at least one successful auction. In view of the failed auctions beginning in February 2008, Noven continues to monitor the market for auction rate securities and consider its impact on the fair market value of Noven s investments. If the fair value of the investments were to decline, management would be required to evaluate whether such decline is other than temporary in accordance with SFAS No. 115. The amount of any impairment that is determined to be temporary would be included in stockholders equity as a component of other comprehensive income or loss. The amount of any such impairment loss that is determined to be other than temporary would be immediately recorded in the consolidated statements of operations. Such a non-cash impairment charge could materially and adversely affect Noven s consolidated financial condition and results of operations.

No unrealized gains and losses have been recognized for the three years ended December 31, 2007. Realized gains and losses and interest and dividends are included in interest income or interest expense, as appropriate.

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As of December 31, 2007 and 2006, Noven s investments in securities consisted of the following (amounts in thousands):

	Fair Value December 31,	
	2007	2006
Tax-exempt variable rate demand bonds	$ 4,000	$ 60,360
Tax-exempt municipal auction rate securities, subsequently liquidated	17,565	67,790
Taxable municipal auction rate securities		2,900
Dividend preferred auction rate securities		2,500
Commercial paper		10,905
Investments, current	21,565	144,455
Tax-exempt municipal auction rate securities, non-current	32,835	
Total investments in securities	$ 54,400	$ 144,455

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. The value of the AMI is neither included in Daytrana product revenues nor 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. Shire has a reciprocal obligation to pay Noven if the yield requirements are exceeded. Noven exceeded the yield requirements for the year ended December 31, 2007, resulting in a $0.2 million payment from Shire to Noven, which reduced cost of products sold. For the year ended December 31, 2006, Noven reimbursed Shire approximately $0.4 million for excess AMI used in production, which amount is included in cost of products sold. During 2007 and 2006, Noven used $5.9 million and $4.0 million of

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Shire s AMI in the finished product, respectively, and had $2.6 million and $1.0 million of Shire s consignment AMI inventory on hand at December 31, 2007 and 2006, respectively, which is not reflected in the table below.

Inventories are stated at the lower of cost (first-in, first-out method, or FIFO) 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 and customers based on market conditions, including levels of competition.

The following are the major classes of inventories as of December 31, 2007 and 2006 (in thousands):

	2007	2006
Finished goods	$ 3,171	$ 893
Work in process	1,532	2,851
Raw materials	7,433	4,907
	$ 12,136	$ 8,651

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. Abnormal amounts of idle facility expense, freight, handling costs and spoilage are charged to operations as incurred in accordance with SFAS No. 151 Inventory Costs, an amendment of ARB No. 43, Chapter 4.

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PROPERTY, PLANT AND EQUIPMENT:

Property, plant and equipment consist of the following at December 31, 2007 and 2006 (in thousands, except estimated useful lives):

	2007	2006	Estimated Useful Lives (in years)
Land	$ 2,540	$ 2,540	
Building and improvements	3,416	3,288	40
Leased property and leasehold improvements	22,400	21,529	10-31
Manufacturing and other equipment	26,181	24,036	3-10
Furniture	2,628	2,339	10
Software and software development costs	5,141	5,101	3
	62,306	58,833	
Less accumulated depreciation and amortization	(26,093)	(21,823)	
	$ 36,213	$ 37,010	

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 2007, 2006, and 2005 depreciation expense totaled $4.4 million, $4.0 million, and $2.7 million, respectively.

SOFTWARE AND DEVELOPMENT COSTS:

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 date at which the project is substantially complete and ready for its intended purpose. For the years ended December 31, 2007, 2006 and 2005, approximately $30,000, $0.9 million and $1.2 million, respectively, of such costs were capitalized.

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

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

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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.

GOODWILL AND INTANGIBLE ASSETS:

Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded by either the pattern in which the economic benefit is expected to be realized or the straight-line method as appropriate. Noven reviews the original estimated useful lives of assets as well as the pattern in which the economic benefit is expected to be realized at least annually and makes adjustments when events indicate that the period and the pattern of economic benefit should be adjusted.

Noven accounts for acquired businesses using the purchase method of accounting, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business based on estimates of their respective fair values. Amounts allocated to acquired in-process research and development are charged to operations at the date of acquisition. Intangible assets are amortized over the expected lives of the assets. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The purchase price allocation for the JDS acquisition was substantially complete as of December 31, 2007. Noven is in the process of finalizing the determination of certain amounts that were subject to post-closing adjustments. However, adjustments to the purchase price resulting from such items are not expected to be material.

The judgments made in determining the estimated fair values assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact Noven s results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. This process requires Noven to make estimates with respect to future sales volumes, pricing, new product launches, anticipated product costs and overall market conditions. Because these estimates influence the values assigned to the various assets acquired, these estimates are considered to be critical accounting estimates. As a result of Noven s acquisition of JDS, in addition to the value of acquired tangible assets and assumed liabilities, Noven recorded on its balance sheet $38.5 million of identifiable intangible assets and $14.7 million of goodwill.

Noven s goodwill is assigned to its Noven Therapeutics segment. Goodwill is reviewed annually for impairment in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying amount of the goodwill may not be recoverable. If Noven determines at the date of the evaluation that the fair value of the reporting segment is less than its carrying value, then Noven would allocate the fair value of the segment to all of the assets and liabilities of the reporting segment in a manner similar to the allocation of purchase price in a business combination. A goodwill impairment would be recognized to the extent that the carrying value of goodwill exceeds the fair value not allocated to identifiable assets. In accordance with SFAS No. 141, Noven s finite-lived intangible assets are evaluated for impairment whenever events or circumstances indicate that the carrying amounts may not be

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recoverable. Noven would recognize an impairment to the extent that the carrying value of a finite-lived intangible exceeds its fair value.

As of December 31, 2007, Noven determined that no impairment of goodwill or intangible assets existed. Noven will continue to assess the carrying value of its goodwill and intangible assets in accordance with applicable accounting guidance. See Note 7 Goodwill and Intangible Assets for additional information.

PATENT DEVELOPMENT COSTS:

Costs related to the development of patents, principally legal fees, are capitalized and amortized over the shorter of the pattern in which the economic benefit is expected to be realized or their remaining legal lives and are included in cost of products sold.

INCOME TAXES:

Income taxes have been provided for using an asset and liability approach in which deferred tax assets and liabilities are recognized for the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is provided when, based on available evidence, it is more likely than not that a portion of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for changes in enacted tax rates and laws.

On January 1, 2007, Noven adopted the provisions of, and began accounting for uncertainty in income taxes in accordance with, Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109 (FIN 48). This interpretation requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before recognition in the financial statements. FIN 48 requires a two-step approach when evaluating a tax position based on recognition (Step 1) and measurement (Step 2).

In the ordinary course of business there is inherent uncertainty in quantifying income tax positions. In accordance with FIN 48, Noven assesses income tax positions and records tax benefits for all years subject to examination based upon management s evaluation of the facts, circumstances and information available at the reporting dates. For those tax positions with a greater than 50% likelihood of being realized, Noven records the benefit. For those income tax positions where it is more likely than not that a tax benefit will not be sustained, no tax benefit is recognized in the consolidated financial statements. When applicable, associated interest and penalties are recognized as a component of interest expense. Upon adoption of FIN 48, and as a result of the recognition and measurement of Noven s tax positions as of January 1, 2007, Noven recognized a charge of approximately $0.5 million to the January 1, 2007 retained earnings balance.

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. Federal tax returns for years 2004 2006 remain open and subject to examination by the Internal Revenue Service. Noven files and remits state income taxes in various states where Noven has

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determined it is required to file state income taxes, and Noven s filings with those states remain open for audit, inclusively, for the years 2003 2006. Noven is not aware of any examinations currently taking place related to its income taxes in any jurisdiction. It is possible that examinations may be initiated by any jurisdiction where Noven operates, or where it can be determined that Noven operates, the results of which may increase Noven s income tax liabilities or decrease the amount of deferred tax assets and may also materially change the amount of unrecognized income tax benefits for tax positions taken.

COMMITMENTS AND CONTINGENCIES:

Noven accounts for commitments and contingencies in accordance with the provisions of SFAS No. 5, Accounting for Contingencies . SFAS No. 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 5 and 17).

REVENUE RECOGNITION:

Product Revenues

Product revenues include: (i) revenues on product sales, net of allowances for product returns and other sales allowances, including allowances for discounts, rebates, and chargebacks; and (ii) royalties from the sale of certain Noven products by licensees.

Substantially all of Noven Transdermals product revenues relate to the sale of transdermal product to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis Pharma), Shire and sanofi-aventis (Aventis) (see Notes 5 and 15). All of Noven Therapeutics product revenues relate to the commercial sale of its two FDA-approved products, Lithobid® and Pexeva®. Revenues from product sales are recognized when both title and the risks and rewards of ownership have been transferred to the buyer. Certain of Noven Transdermals 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 by that licensee. Noven receives the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. Noven records any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, Noven records the adjustments when payments from licensees are received. These amounts are included in product revenues.

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Royalty revenues consist of royalties payable by Novogyne and Novartis Pharma on sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. Noven accrues royalty revenues and receivables 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.

Product revenues are recorded net of allowances for returns, if any. The methodology used by Noven to estimate product returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Sales allowances for estimated discounts, rebates, returns, chargebacks and other sales allowances are established by Noven concurrently with the recognition of revenue. Sales allowances are established based upon consideration of a variety of factors, including prescription data, customers inventory reports and other information received from customers and other third parties related to product in the distribution channel, customers right of return, historical information by product, the number and timing of competitive products approved for sale, both historically and as projected, the estimated size of the market for Noven s products, current and projected economic and market conditions, anticipated future product pricing, future levels of prescriptions for the products and analyses that are performed. Management believes that the sales allowances are reasonably determinable and are based on the information available at that time to arrive at the best estimate.

The key assumptions management uses to arrive at its best estimate of sales allowances are its estimates of inventory levels in the distribution channel, future price changes and potential returns, as well as historical information by product. The estimates of prescription data, inventory at customers and in the distribution channel are subject to the inherent limitations of estimates that rely on third party data, as certain third party information may itself rely on estimates, and reflect other limitations. Chargebacks, discounts and allowances for doubtful accounts are estimated based on historical payment experience, historical relationships to revenues and contractual arrangements. Management believes that such estimates are readily determinable due to the limited number of assumptions involved and the consistency of historical experience.

Estimated rebates and returns involve more subjective judgments and are more complex in nature. Actual product returns, rebates and other sales allowances incurred are dependent upon future events. Management periodically monitors the factors that influence sales allowances and makes adjustments to these provisions when it believes that actual results may differ from established allowances. If conditions in future periods change, revisions to previous estimates may be required, potentially by significant amounts. Changes in the level of provisions for estimated product returns, rebates and other sales allowances will affect revenues.

Sales allowances for estimated discounts, chargebacks and doubtful accounts are recorded as reductions to accounts receivable. Allowances for product returns, estimated Medicaid, managed care and certain other rebates are recorded as other accrued liabilities. Sales allowances are included in the consolidated balance sheets as of December 31, as follows (in thousands):

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	2007	2006
Accounts receivable:		
Gross receivable	$ 7,208	$ 5,105
Sales allowances and allowances for doubtful accounts	(252)	(67)
Accounts receivable, net	$ 6,956	$ 5,038
Sales allowances:		
Accrued medicaid rebates	$ 4,065	$
Allowance for product returns	1,875	426
Other sales allowances	770	
Total sales allowances	$ 6,710	$ 426

License Revenues and Multiple Element Arrangements

License revenues include up-front, milestone and similar payments under license agreements. These agreements may contain multiple deliverables, such as product development, technology licenses, contract research and development, and the manufacturing and supply of products.

Noven recognizes license revenue in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin (SAB) Topic 13, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, as applicable. Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has standalone value to the customer, and whether there is objective, reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values or using the residual method, as appropriate, and the applicable revenue recognition criteria are identified and applied to each of the units. If multiple deliverables do not meet the separation criteria of EITF Issue 00-21, they are accounted for as a single unit of accounting and management applies a revenue recognition method that best reflects the economic substance of the transaction. In selecting the appropriate method to apply, management considers the specific facts and circumstances of each transaction, giving particular emphasis to the manner in which the customer receives the benefit of the transaction.

In general, revenues from nonrefundable, up-front license fees received prior to or upon product approval are deferred until the revenue recognition criteria have been satisfied and the customer begins to derive the value and benefits from the use of, or access to, the license. Noven s obligations generally are completed upon achieving regulatory approval of the licensed products, upon delivery of Noven s development work, or when Noven has delivered a commercially viable license to its technology. In multiple element arrangements where research and development work does not meet the separation criteria of EITF Issue 00-21 (as has typically been the case for Noven s agreements), Noven s policy is to recognize such revenues over the product s estimated life cycle. Noven s arrangements generally culminate in the delivery to the licensee of technology licenses to market and sell Noven-developed products in a licensed territory. Consequently, applying the guidance of EITF Issue 00-21, management has determined that these deliverables should be accounted for as a single unit of accounting. Furthermore, management has concluded that the most appropriate revenue attribution method is

to defer license revenues and recognize them over the products estimated life cycles, as the customer derives the value from the use of, or access to, the license. When management is unable to estimate the pattern of the expected economic benefits, the deferred revenues are amortized on a systematic and rational (straight-line) basis over the product s estimated life cycle.

Noven evaluates the facts and circumstances surrounding achievement of nonrefundable sales milestones to ensure that revenue recognition represents the substance of the transaction. Substantive sales milestones are recognized as revenue when achieved based on the substance of the underlying transactions, when the Company has fulfilled all of its obligations relative to the milestone payments. Non-substantive sales milestones are not recognized immediately as revenue when achieved, but are deferred and recognized as revenues over time in a manner that is consistent with the underlying facts and circumstances.

In order to determine the products estimated life cycles over which Noven recognizes license revenues, Noven considers the remaining life of proprietary protection and the economic lives of competing products in the specific or similar therapeutic categories for comparison in determining the product life cycles. Noven believes the estimated product life cycle (the estimated economic life) is generally determined to come to a conclusion when prescription trends decline to less than 20% of the product s peak prescriptions, which can be impacted by introductions of competing branded products, generic competition, and/or changes/improvements in forms of treatment therapy.

In the event that Noven receives a nonrefundable payment for a product that does not ultimately receive regulatory approval, the payment is recognized as revenue when all efforts cease, the project has been discontinued and Noven has no further obligation relating to the product.

In 2003 and 2004, Noven entered into two sets of collaboration agreements with Shire:

A 2003 agreement consisting primarily of the transfer to Shire of a license to market and sell Daytrana and a manufacturing and supply agreement under which the Company agreed to supply product to Shire; and

A 2004 agreement, as amended, to develop an amphetamine-based transdermal patch to treat ADHD and a related license agreement.

Key elements of these agreements are described in Note 5 Contract and License Agreements. Noven s revenue recognition related to these agreements is described below.

Shire Collaboration Daytrana

Under the Shire Daytrana collaboration arrangement, Noven determined that there were three deliverables: (1) a license; (2) a research and development arrangement; and (3) a manufacturing and supply agreement.

The license and research and development deliverables in this agreement did not meet the criteria for separation under EITF 00-21; therefore, they were combined and accounted for as a single unit of accounting. Noven concluded that the manufacturing and supply agreement was at

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fair value based on Noven s experience with similar arrangements; as a result, it was accounted for separately from the single unit of accounting (license and research and development deliverable). Accordingly, all milestone payments (including the up-front payment, FDA approval payment and subsequent sales milestones) were allocated to the single unit of accounting. In accordance with Noven s policy, Noven began to recognize revenue for the single unit of accounting when the revenue recognition criteria related to all deliverables had been satisfied. Specifically, this occurred upon FDA approval of Daytrana in April 2006, at which time all of Noven s obligations were satisfied, Shire had a commercially viable license and Shire began realizing the value of the deliverable.

Since this agreement provides for multiple payment streams, Noven recognizes revenue as a single unit of accounting using a single attribution model for the license and research and development deliverable, whereby all milestone payments are recognized using the straight-line method over the estimated life cycle of Daytrana (estimated to be seven years), as Shire derives the value from the use of, or access to, the license.

Shire Collaboration Amphetamine

In connection with the 2004 amphetamine collaboration, Shire paid Noven a nonrefundable payment of $1.0 million in August 2006, in exchange for the option to purchase, for an additional $5.9 million, the exclusive developmental rights to the product. The agreement, as amended, provided that Noven would perform certain early-stage development activities. Noven completed a Phase 1 clinical study for the product in March 2007. In June 2007, Shire exercised its option to acquire the exclusive development rights to the product and Noven received the $5.9 million option payment.

Simultaneous with the $5.9 million payment, Noven agreed to modify the patch formulation in order to align the amphetamine patch with Shire s future direction in the ADHD market. Shire has agreed to pay Noven for its development efforts in this regard. Applying the guidance in EITF Issue 00-21, the development agreement for the new formulation is, in essence, a modification and continuation of the original development agreement and, as a result, the total $6.9 million arrangement consideration is considered a single unit of accounting. This $6.9 million arrangement consideration was included in deferred license and contract revenues on Noven s consolidated balance sheet as of December 31, 2007.

Noven has agreed to deliver a combination of development work and a license to market and sell this new product. Applying the guidance of EITF Issue 00-21, Noven concluded that the license does not have standalone value to Shire absent completion of Noven s development efforts. Thus, the deliverables have been combined into a single unit of accounting. Revenue recognition will commence when the license has been delivered, Noven has fulfilled its obligations and Shire begins realizing the value of the license deliverable related to this product. The $6.9 million and any additional consideration will be amortized on a systematic and rational (straight-line) basis over the product s estimated life cycle including Shire s development period, as Noven s performance and obligations will be complete once delivery of the license takes place.

Contract Revenues

Contract revenues consist of contract payments related to research and development projects performed for third parties where Noven has determined that such projects are separate

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units of accounting. The work performed by Noven may include feasibility studies to determine if a specific drug can be delivered transdermally, 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 nonrefundable up-front payments received prior to commencing work, Noven recognizes revenue based on the proportional performance method as research and development work is performed by Noven. Additional payments upon completion of additional phases and milestone payments are recognized when the specified performance criteria are achieved under the milestone method as long as such milestones are substantive. The difference between the amount of the payments received and the amount recognized is recorded as deferred license and contract revenues on Noven s consolidated balance sheet until such amount is earned.

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.

SHIPPING AND HANDLING COSTS:

Shipping and handling costs are included in cost of goods sold and were not significant for the period from the Closing Date through December 31, 2007.

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 charged to operations as incurred and include direct and allocated expenses, which include 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 costs associated with each of these functions.

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ADVERTISING COSTS:

Advertising costs are charged to operations as incurred. In addition, Noven Therapeutics regularly carries inventory of sample product for distribution in the marketplace; however, Noven s policy is to immediately expense samples when the title and risk of loss for the samples transfers to Noven. Samples expense is included in selling, general and administrative expenses.

EARNINGS (LOSS) PER SHARE:

Noven computes its earnings (loss) per share in accordance with SFAS No. 128, Earnings Per Share . Basic earnings (loss) 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 (loss) per share calculation if the effect of their inclusion would be antidilutive. The total number of common stock equivalents not included in the diluted earnings (loss) per share calculation for the years ended December 31, 2007, 2006 and 2005 were 1,668,960, 421,813 and 2,019,863 shares, respectively, which amounts represent out-of-the-money equity awards. Noven incurred a net loss for the year ended December 31, 2007. As a result, 418,008 in-the-money options and/or stock settled appreciation rights were excluded from the diluted loss per share calculation as their effect would be antidilutive.

COMPREHENSIVE INCOME (LOSS):

For the years ended December 31, 2007, 2006 and 2005, comprehensive income (loss) was equal to net income (loss).

STOCK-BASED COMPENSATION PLANS:

On January 1, 2006, Noven adopted the provisions of, and began accounting for stock-based compensation in accordance with, SFAS No. 123 Revised, Share Based Payment (SFAS No. 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 No. 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 in accordance with SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123).

Noven currently uses the Black-Scholes option pricing model to determine the fair value of stock options and stock-settled 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

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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 using the average of the vesting term and the contractual term of the option, as described in SAB 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/SSAR. Noven bases the risk-free interest rate that Noven uses in the option valuation model on United States Treasury zero-coupon issues with remaining terms similar to the expected term on the options/SSARs. 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 awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. The weighted average grant date fair values of each option/SSAR granted during 2007, 2006 and 2005 are estimated to be $6.67, $10.94 and $8.64, respectively, on the dates of the grants using the Black-Scholes option-pricing model with the assumptions below:

	Years Ended December 31,		
	2007	2006	2005
Volatility	48.5%	49.2%	69.0%
Risk free interest rate	3.90%	4.67%	4.30%
Expected life (years)	5	5	5
Dividend yield	0%	0%	0%

Total stock-based compensation recognized in Noven s consolidated statements of operations for the years ended December 31, 2007 and 2006 were as follows (in thousands):

	2007	2006
Selling, general and administrative	$ 4,522	$ 2,458
Research and development	543	412
Total cost of products sold	316	416
	$ 5,381	$ 3,286
Tax benefit recognized related to stock-based compensation expense	$ 1,861	$ 941

Prior to the adoption of SFAS No. 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 statements of cash flows.

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SFAS No. 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 that reported under prior accounting rules. Cash received from options exercised under all share-based payment arrangements for the years ended December 31, 2007, 2006 and 2005 was $2.5 million, $13.2 million and $1.3 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled $0.5 million, $3.6 million and $0.3 million for the years ended December 31, 2007, 2006 and 2005, respectively, of which $0.4 million and $2.6 million was reported as a financing cash flow for the years ended December 31, 2007 and 2006, respectively. There was no amount reported as financing cash flow for the year ended December 31, 2005. The total intrinsic values of all option exercises for each of the years ended December 31, 2007, 2006 and 2005 were $1.6 million, $10.5 million and $0.9 million, respectively.

At December 31, 2007, 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 No. 123(R), is approximately $9.4 million before the effect of income taxes, of which $3.6 million, $2.8 million, $2.0 million and $1.0 million are expected to be incurred in 2008, 2009, 2010 and 2011, respectively.

In accordance with the modified prospective transition method, Noven s financial statements for periods before 2006 have not been restated and do not include the impact of SFAS No. 123(R). Accordingly, no compensation expense related to equity awards was recognized in 2005, as all stock options granted had an exercise price equal to the fair market value of the underlying common stock on the dates of grant. The following table shows the effect on 2005 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 of SFAS No. 123(R) (in thousands, except per share amounts):

	2005
Net income:	
As reported	$ 9,972
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(14,145)
Pro forma net loss	$ (4,173)
Basic earnings per share:	
As reported	$ 0.42
Pro forma loss per share	$ (0.18)
Diluted earnings per share:	
As reported	$ 0.42
Pro forma loss per share	$ (0.18)

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In order to eliminate some of the future compensation expense that Noven would have otherwise recognized in its statements of operations upon adoption of SFAS No. 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 statements of operations and included in the pro forma footnote disclosure above for 2005.

During 2007, Noven recorded expenses of approximately $3.3 million associated with the separation of three executive officers, including the former chief executive officer and former chief financial officer. Approximately $1.9 million represented cash separation payments, which will be paid in 2008. The remainder of the charge consisted of $0.7 million related to extending the term of their vested equity awards and $0.7 million representing the fair value of restricted stock awarded to the former chief executive officer. In addition, on the Closing Date of the JDS acquisition, Noven entered into a non-competition agreement with an executive of JDS who agreed to serve on Noven s board of directors following the acquisition. This obligation, valued at $0.3 million, was settled by granting 44,297 SSARs. This non-competition agreement has been recorded as an intangible asset on Noven s consolidated balance sheet and is being charged to operations over the non-competition period. The separation payments, as well as the amortization costs of the non-competition agreement are included in selling, general and administrative expenses in the accompanying 2007 consolidated statement of operations.

FAIR VALUE OF FINANCIAL INSTRUMENTS:

The carrying amounts of financial instruments such as cash and cash equivalents, accounts receivable, accounts payable and accrued expenses reasonably approximate fair values because of the short term nature of these items. Investments are carried at fair value.

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. In addition, Noven Therapeutics customers currently consist of wholesalers and large-chain pharmacy stores. 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. See Note 15 Segment and Customer Data for information on revenues by customer.

RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin (ARB) No. 51 , SFAS No. 160 establishes accounting and reporting standards for the noncontrolling interest (minority interest) in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 amends certain of ARB 51 s consolidation procedures to conform them to the requirements of SFAS No. 141(R), Business Combinations , which was issued at the same time as this

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Statement, SFAS No. 160. This new statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008 (that is, January 1, 2009, for entities with calendar year-ends). Earlier adoption is prohibited. SFAS No. 160 will be applied prospectively as of the beginning of the fiscal year in which this Statement is initially applied, except for the presentation and disclosure requirements, which will be applied retrospectively for all periods presented. Noven is currently assessing the impact of adopting SFAS No. 160 and the impact it may have on Noven s consolidated results of operations, financial condition and cash flows.

In December 2007, the FASB revised SFAS No. 141, Business Combinations (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer: (i) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; (ii) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and (iii) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) applies to all transactions or other events in which an entity (the acquirer) obtains control of one or more businesses (the acquiree), including those sometimes referred to as true mergers or mergers of equals and combinations achieved without the transfer of consideration, for example, by contract alone or through the lapse of minority veto rights. SFAS No. 141(R) does not apply to: (i) the formation of a joint venture; (ii) the acquisition of an asset or a group of assets that does not constitute a business; (iii) a combination between entities or businesses under common control; or (iv) a combination between not-for-profit organizations or the acquisition of a for-profit business by a not-for-profit organization. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply SFAS No. 141(R) before that date. Noven is currently assessing the impact of adopting SFAS No. 141(R) and the impact it may have on Noven s consolidated results of operations, financial condition and cash flows.

In December 2007, the FASB s Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 07-01, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property (EITF 07-01). EITF 07-01 discusses the appropriate income statement presentation and classification for the activities and payments between the participants in arrangements related to the development and commercialization of intellectual property. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. The sufficiency of disclosure related to these arrangements is also specified. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. Noven is currently assessing the impact of adopting EITF 07-01 and the impact it may have on Noven s consolidated results of operations, financial condition and cash flows.

In June 2007, the EITF issued EITF Issue No. 07-03, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-03). This EITF requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. Entities should continue to

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evaluate whether they expect the goods to be delivered or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to operations. EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Noven is currently assessing the impact of adopting EITF 07-03 and the impact it may have on Noven s consolidated results of operations, financial condition and cash flows.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of SFAS No. 115 . This Statement permits entities to choose to measure many financial instruments and certain other items at fair value and applies to all entities. Most of the provisions of this Statement apply only to entities that elect the fair value option. However, the amendment to SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Noven is currently assessing the impact of adopting SFAS No. 159 and the impact it may have on Noven s consolidated results of operations, financial condition and cash flows.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. This standard defines fair value, establishes a framework for measuring fair value in U.S. GAAP, and expands disclosure about fair value measurements. This standard applies under other accounting pronouncements that require or permit fair value measurements, but does not require any new fair value measurements. In February 2008 the FASB issued FASB Staff Position (FSP) 157-2 Effective Date of FASB Statement No. 157 . Under FSP 157-2, the provisions of SFAS No. 157 will be adopted for financial instruments in 2008 and, when required, for nonfinancial assets and nonfinancial liabilities in 2009 (except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis). Adoption of SFAS No. 157 is not expected to materially affect Noven s consolidated financial statements. However, as a result of illiquid conditions in the market for auction rate securities beginning in February 2008, Noven may be required to employ inputs other than quoted prices in active markets for identical securities in order to value its investments. SFAS No. 157 would require disclosure about the inputs used to determine the fair value of Noven s investments.

3. CASH FLOW INFORMATION:

Cash payments for income taxes totaled $23.7 million, $0.8 million and $1.6 million in 2007, 2006, and 2005, respectively. Cash payments for interest totaled $35,000, $15,000, and $12,000 in 2007, 2006 and 2005, respectively.

Non-cash Operating Activities

The State of New Jersey requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. In 2007, 2006, and 2005, Novogyne paid $6.0 million, $2.2 million and $1.5 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 distributions to Noven from Novogyne.

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Noven recorded a $0.5 million, $3.6 million and $0.3 million income tax benefit as additional paid-in capital derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options in 2007, 2006 and 2005, respectively.

Non-cash Investing Activities

On the Closing Date, Noven entered into a non-competition agreement with an executive of JDS who agreed to serve on Noven s board of directors following the acquisition. This obligation, valued at $0.3 million, was settled by granting 44,297 SSARs. This non-competition agreement has been recorded as an intangible asset on Noven s consolidated balance sheet as of December 31, 2007.

In 2007 and 2006, Noven entered into capital lease obligations totaling $0.1 million, and $0.4 million for new equipment, respectively. Noven did not enter into any capital leases in 2005.

In 2005, Noven recorded approximately $0.9 million in leasehold improvements as a deferred rent credit relating to landlord-funded leasehold improvements. See Note 9 Operating and Capital Leases .

4. ACQUISITION OF JDS PHARMACEUTICALS, LLC:

Noven acquired JDS (subsequently re-named Noven Therapeutics, LLC) on August 14, 2007 pursuant to the terms of the Agreement and Plan of Merger, dated July 9, 2007 (the Merger Agreement), among Noven, Noven Acquisition, LLC, a Delaware limited liability company and an indirect wholly owned subsidiary of Noven (Merger Sub), JDS and Satow Associates, LLC, solely in its capacity as representative of the equity holders of JDS (the Member Representative). On the Closing Date, Merger Sub merged with and into JDS (the Merger), with JDS continuing as the surviving company and as an indirect wholly owned subsidiary of Noven following the Merger.

The purchase price for the acquisition was $125.0 million cash paid at closing, subject to certain working capital adjustments (the Merger Consideration). On the Closing Date, a portion of the Merger Consideration in an amount equal to $10.0 million was placed in an escrow account to be held until December 31, 2008 to satisfy any post-closing indemnity claims by Noven in connection with the Merger Agreement as well as certain expenses incurred by the Member Representative. Any adjustments resulting from these post-closing indemnity claims will effectively modify the consideration paid by Noven. The Merger Consideration, which Noven funded from the sale of short-term investments, was paid at closing to the Member Representative for the benefit of holders of outstanding equity interests of JDS prior to the Merger.

The total purchase price for the JDS acquisition consisted of $125.0 million cash paid at closing, approximately $5.4 million of transaction costs, consisting primarily of fees paid for financial advisory, legal, valuation and accounting due diligence services, and approximately $0.5 million in connection with non-competition agreements entered into with two executives of JDS in connection with the Merger. The executives were the former Chief Executive Officer (the JDS CEO) and former President (the JDS President) of JDS who are father and son, respectively. The former JDS CEO became a member of Noven s Board of Directors after the Merger.

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In addition to the non-competition agreements which were included in the purchase price, the Company also entered into a one-year consulting agreement with the JDS CEO to provide consulting services with respect to JDS business as may reasonably be requested by Noven in exchange for a service fee of $250 per hour. Pursuant to the consulting agreement, Noven has also agreed to provide the former JDS CEO with the use of a Noven office and secretarial support. Noven paid the former JDS CEO $37,500 in 2007 under the consulting agreement which was charged to operations. In addition, Noven entered into a six month employment agreement with the former JDS President. Salary and bonus payments totaling $162,400 under the employment agreement were charged to operations during 2007. The balance of $33,100 due under the employment agreement will be charged to operations during 2008.

The acquisition of JDS was accounted for using the purchase method of accounting. The purchase price was allocated to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the Closing Date. The purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by approximately $14.7 million, which has been recorded as goodwill, all of which is deductible for tax purposes. The primary factors that contributed to the recognition of goodwill in Noven s acquisition of JDS are the intellectual capital of the skilled sales, marketing and distribution personnel and an organized experienced pharmaceutical sales force that is leveragable, neither of which meet the criteria for recognition as an asset separately from goodwill.

The following table presents the allocation of the total purchase price for the acquisition of JDS (amounts in thousands):

Current assets, including cash of $0.6 million	$ 8,268
Property and equipment	362
Intangible assets:	
Acquired in-process research and development	100,150
Identifiable intangible assets	38,547
Goodwill	14,734
Other assets	163
Accrued expenses and other current liabilities	(16,088)
Long-term obligation assumed	(3,711)
Contingent milestones assumed	(11,500)
Total purchase price	$ 130,925

Acquired In-Process Research and Development (IPR&D) Intellectual Property

IPR&D is defined by FASB Interpretation No. 4, Applicability of SFAS Statement No. 2 to Business Combinations Accounted for by the Purchase Method (FIN 4), as being a development project that has been initiated and achieved material progress but: (i) has not yet reached technological feasibility or has not yet reached the appropriate regulatory approval; (ii) has no alternative future use; and (iii) the fair value is estimable with reasonable certainty. As required by FIN 4, the portion of the purchase price allocated to in-process research and development expenses (IPR&D) of $100.2 million was immediately charged to operations

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following the completion of the acquisition and is reflected in Noven s consolidated statement of operations for the year ended December 31, 2007.

A project-by-project valuation using the guidance in SFAS No. 141 and the American Institute of Certified Public Accountants Practice Aid Assets Acquired in a Business Combination to Be Used In Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries has been conducted to determine the fair value of JDS s research and development projects that were in-process, but not yet completed as of the completion of the Merger.

The fair value of IPR&D has been determined by the income approach using the multi-period excess earnings method. The value of the projects has been based on the present value of probability adjusted incremental cash flows, after the deduction of contributory asset charges for other assets employed (including fixed assets, the assembled workforce and working capital). The probability weightings used to determine IPR&D cash flows ranged from 80% to 90%. The discount rate used to determine the present value of IPR&D cash flows was approximately 23%.

The forecast of future IPR&D cash flows required various assumptions to be made including:

- revenue that is likely to result from IPR&D projects, including estimated number of units to be sold, estimated selling prices, estimated market penetration, estimated market share, estimated year-over-year growth rates over the product life cycles and estimated sales allowances;
- cost of sales for the potential product using historical data, industry data or other sources of market data;
- sales and marketing expenses using historical data, industry data or other sources of market data;
- general and administrative expenses; and
- research and development expenses.

In addition, Noven considered the following in determining the fair value of IPR&D:

- the projects stage of completion;
- the costs incurred to date;
- the projected costs to complete the IPR&D projects;
- the contribution, if any, of the acquired identifiable intangible assets;
- the projected launch date of the products under development;
- the estimated life of the products under development; and
- the probability of success of launching a commercially viable product.

To the extent that an IPR&D project is expected to utilize the acquired identified intangible assets, the value of the IPR&D project has been reduced to reflect this utilization.

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Identifiable Intangible Assets

The identifiable intangible assets acquired are attributable to the following categories: (dollar amounts in thousands):

	Fair Value	Asset life years[1]
Acquired product intangibles	$ 37,790	6 - 10
Non-competition agreements	530	2 - 3
Favorable lease	227	10 months
Total identifiable intangible assets	$ 38,547	

(1) Asset lives represent the economic periods of benefit over which management believes the assets will contribute to the future cash flows of Noven.

Intellectual Property approved products

The fair value of the intellectual property rights (including technical processes and institutional understanding) associated with JDS s products approved by the FDA has been determined by the income approach using the multi-period excess earnings method. Using the multi-period excess earnings method, the approved products intellectual property fair values have been based on the present value of the incremental after-tax cash flows attributable to the assets, after the deduction of contributory asset charges for other assets employed (including fixed assets, the assembled workforce and working capital). The forecast of future cash flows for approved products requires various assumptions as discussed in Acquired In-Process Research and Development (IPR&D) Intellectual Property above.

The valuations of IPR&D intellectual property and identifiable intangible assets are based on information available at the time of the acquisition and the expectations and assumptions that: (i) have been deemed reasonable by Noven s management; and (ii) would be available to, and made by, a market participant. No assurance can be given that the underlying assumptions or events incorporated into the valuations of such assets will occur as projected. For these reasons, among others, the actual cash flows may vary materially from forecasted future cash flows.

Non-competition agreements and favorable lease

In accordance with SFAS No. 141, the fair values of non-competition agreements and a favorable lease entered into in connection with the acquisition were recorded as intangible assets and are being amortized on a straight-line basis over their expected periods of benefit.

Long-term liabilities

Noven assumed a long-term obligation in the Merger and, in accordance with SFAS No. 141 and EITF Issue No. 98-1, Valuation of Debt Assumed in a Purchase Business Combination , this liability was assigned an estimated fair value of $3.7 million based on the present value of the estimated future cash flows at the date of acquisition. The long-term obligation was paid in full by Noven in 2007 based on an analysis of favorable early payment discount.

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Noven also assumed approximately $11.5 million in purchase price contingent sales milestones related to JDS s acquisition of Pexeva® from Synthon Pharmaceuticals, Inc. As of the acquisition date, Noven determined that it was probable that these contingent sales milestones would be paid. Therefore, in accordance with SFAS No. 141, the contingent sales milestones were recorded as liabilities in the amount of $11.5 million. The contingent sales milestones consist of the following:

$1.0 million milestone payable when annual net sales of Pexeva® equal or exceed $7.0 million but are less than $8.0 million in each of 2007 or 2008, which milestone is increased to $2.0 million if annual net sales exceed $8.0 million in each of 2007 or 2008. Pexeva® net sales exceeded the $8.0 million threshold for the year ended December 31, 2007.

$1.25 million milestone payable for each of the first two years when annual net sales of Pexeva® equal or exceed $10.0 million between 2007 and 2017. Pexeva® net sales exceeded this threshold for the year ended December 31, 2007.

$5.0 million milestone payable in the first year that annual net sales of Pexeva® (or any paroxetine mesylate product) equal or exceed $30.0 million between 2007 and 2017.

Supplemental disclosure of pro forma information

The following represents Noven s pro forma results of operations as though the acquisition of JDS had occurred on January 1, 2006. As described above, the fair value of IPR&D projects acquired which had not yet reached approval totaling $100.2 million was immediately charged to operations following the acquisition. This amount has been excluded from the pro forma results because it results directly from the transaction and is non-recurring in nature. The pro forma information is not necessarily indicative of the results that would have resulted had the acquisition occurred at the beginning of the periods presented, nor is it necessarily indicative of future results. The pro forma information for the years ended December 31, 2007 and 2006 is as follows (amounts in thousands, except per share data):

	2007	2006
Net revenues	$97,891	$80,395
Net income	8,246	5,168
Net earnings per share (Basic)	0.33	0.22
Net earnings per share (Diluted)	0.33	0.21

5. CONTRACT AND LICENSE AGREEMENTS:

HORMONE THERAPY COLLABORATIONS

Noven has license agreements relating to its hormone therapy products with Aventis, Novartis, Novartis Pharma and Novogyne. At the time of the formation of Novogyne, Novartis sublicensed its rights under its license agreement to Novogyne. Noven s agreement with

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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 Sanofi Aventis as successor in interest of 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 (approximately $0.2 million as of December 31, 2007), 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, 2007 and 2006, the carrying amounts of the leased property and deferred revenues were $3.6 million and $3.8 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.

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.

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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 Pharmaceuticals, Inc. (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 designed to determine whether certain compounds identified by the parties could be delivered using Noven s transdermal technology.

In September 2005, the FDA advised Noven that it did not expect to approve its 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 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. 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 that 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 cost of products sold in that quarter.

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 revenues and recognized it as license revenues in the fourth quarter of 2005.

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Noven has granted Endo a right of first negotiation with respect to any reformulated fentanyl patch that Noven may develop. Noven has decided not to pursue the development of a fentanyl patch at this time.

SHIRE COLLABORATION

Noven has developed a once-daily transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder (ADHD) 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 upon closing of the transaction in April 2003; (ii) $50.0 million in April 2006 upon receipt of final marketing approval by the FDA; and (iii) three installments of $25.0 million each 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 received the first $25.0 million sales milestone in the 2007 first quarter, and the second $25.0 million sales milestone in the 2007 third quarter. Noven is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date each milestone was 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. During 2007 and 2006 Noven recognized $14.0 million and $5.9 million, respectively, in license revenues related to the Shire collaboration. Noven also manufactures and supplies finished product to Shire. During 2007 and 2006 Noven s product sales of Daytrana to Shire were $13.4 million and $8.6 million, respectively.

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 that 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 2007, 2006 or 2005, 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 revenues from the date of approval through the first quarter of 2013, which is the estimated life of the product.

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 payment of $1.0 million in August 2006, in

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exchange for the option of purchasing, for an additional $5.9 million, the exclusive developmental rights to the product. The amended agreement further provided that Noven would perform certain early-stage development activities which were previously to be performed by Shire. Noven completed a Phase 1 clinical study for the product in March 2007. In June 2007, Shire exercised its option to acquire the exclusive development rights to the product and Noven received the $5.9 million option payment. This $5.9 million, as well as the initial $1.0 million received from Shire for the grant of the option, was included in deferred license and contract revenues on Noven s balance sheet as of December 31, 2007 due to ongoing and inseparable development obligations and rights owed to Shire. Simultaneous with the $5.9 million payment, Shire requested modifications to the patch formulation in order to align the amphetamine patch with Shire s future direction in ADHD, and has agreed to pay Noven for its development efforts in this regard.

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). 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. Noven did not earn any revenue under this collaboration during 2007. During 2006, and 2005 Noven earned $0.9 million and $0.1 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.

SYNTHON PHARMACEUTICALS COLLABORATION

In November 2005, JDS entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc. (Synthon) for the purchase of Pexeva®. In this transaction, JDS purchased certain assets related to Pexeva® including the New Drug Application (NDA), intellectual property (including patents and trademarks) and certain finished goods inventory. The purchase of Pexeva® included a cash payment at the time of closing and an obligation to make certain future fixed payments and certain contingent payments.

Following the Merger, Noven became responsible for possible future contingent payments of up to $23.5 million under the asset purchase agreement with Synthon which may be payable over the next three to five years. As of December 31, 2007, $11.5 million of these milestones were reflected as liabilities in Noven s consolidated balance sheet. See Note 4 Acquisition of JDS Pharmaceuticals, LLC Long-term Liabilities Assumed.

SOLVAY PHARMACEUTICALS COLLABORATION

In August 2004, JDS entered into an asset purchase agreement with Solvay Pharmaceuticals, Inc. (Solvay) for the purchase of Lithobid®. In this transaction, JDS purchased certain assets related to Lithobid® including the NDA, intellectual property (including trademarks) and certain finished goods inventory, which was paid in full prior to the closing of

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the Merger. In connection with the acquisition of the product rights for Lithobid®, JDS entered into an agreement requiring Solvay to manufacture and supply Lithobid® for up to five years, subject to certain limitations. Prior to Noven s acquisition of JDS, Solvay assigned the manufacturing and supply agreement to ANI Pharmaceuticals, Inc. (ANI). In December 2007, JDS and ANI agreed to terminate the Solvay manufacturing and supply agreement and enter into a new manufacturing and supply agreement containing substantially similar terms and conditions as the prior agreement.

LITHIUM QD

In March 2004, JDS entered into an asset purchase agreement with an unrelated third party to acquire certain United States and international patents and other intellectual property related to a once daily lithium carbonate product (Lithium QD) for the purpose of developing, obtaining regulatory approval, manufacturing and marketing the product in the United States, Canada and certain other countries. The asset purchase agreement provides for potential future payments to the seller of up to $4.0 million subject to the achievement of certain development milestones. JDS has separately entered into an exclusive supply agreement for the manufacture of Lithium QD with another unrelated third party which also provides for additional potential contingent payments of up to $2.0 million. In October 2007, a Phase 3 clinical trial of Lithium QD did not achieve its primary endpoint with statistical significance. The Lithium QD project is currently under analysis and continued development is under evaluation.

BANNER PHARMACAPS COLLABORATION

In April 2007, JDS entered into a development, license and supply agreement with Banner Pharmacaps Inc. (Banner) in which Banner licensed rights to a delayed release valproic acid product (Stavzor), as well as rights to future development of an extended release valproic acid product, in return for a payment at closing, royalties on future sales, and up to $6.0 million in potential development milestone payments. The agreement also provides that Banner will be the exclusive supplier of the products licensed under the agreement.

OTHER AGREEMENTS

Noven has entered into other developmental agreements for feasibility testing of certain compounds. In 2007, 2006 and 2005, Noven received approximately $0.8 million $0.2 million and $1.7 million, respectively, related to these agreements. During 2006, Noven also recognized as revenues a $1.0 million one-time payment from a third party for a license to certain Noven patents because Noven had no continuing involvement or 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.

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

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

The summarized Statements of Operations of Novogyne for the years ended December 31, 2007, 2006 and 2005 are as follows (in thousands):

	Years Ended December 31,		
	2007	2006	2005
Gross revenues	$ 171,347	$ 154,901	$ 136,901
Sales allowances	21,912	17,226	14,408
Sales returns allowances	1,447	5,732	936
Sales allowances and returns	23,359	22,958	15,344
Net revenues	147,988	131,943	121,557
Cost of sales	31,204	30,149	28,696
Selling, general and administrative expenses	38,083	37,318	35,568
Income from operations	78,701	64,476	57,293
Interest income	1,145	841	461
Net income	$ 79,846	$ 65,317	$ 57,754
Noven s equity in earnings of Novogyne	$ 35,850	$ 28,632	$ 24,655

The activity in the Investment in Novogyne account for the years ended December 31, 2007, 2006 and 2005 is as follows (in thousands):

	2007	2006	2005
Investment in Novogyne, beginning of year	$ 23,296	$ 23,243	$ 26,233
Equity in earnings of Novogyne	35,850	28,632	24,655
Cash distributions from Novogyne	(28,844)	(26,368)	(26,187)
Non-cash distribution from Novogyne	(5,992)	(2,211)	(1,458)
Investment in Novogyne, end of year	$ 24,310	$ 23,296	$ 23,243

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

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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 $6.0 million, $2.2 million and $1.5 million in tax payments made in 2007, 2006 and 2005, respectively, to the New Jersey Department of Revenue made by Novogyne on Noven s behalf. As discussed in Note 3 Cash Flow Information , these payments were deemed distributions to Noven from Novogyne.

The summarized Balance Sheets of Novogyne at December 31, 2007 and 2006 are as follows (in thousands):

	December 31,	
	2007	2006
Current assets	$ 36,706	$ 29,447
Insurance receivable	6,772	7,299
Intangible assets	20,083	26,263
Total assets	$ 63,561	$ 63,009
Product liability reserve	8,976	9,629
Allowance for returns	6,036	7,938
Other liabilities	10,174	8,943
Total liabilities (all of which are current)	25,186	26,510
Members capital	$ 38,375	$ 36,499

The activity for the allowance for returns for the years ended December 31, 2006 and 2007 is as follows (in thousands):

Balance January 1, 2006	$ 6,168
Expense related to expired product-current year	4,342
Revision to prior year expense estimate	1,390
Deductions	(3,962)
Balance December 31, 2006	7,938
Expense related to expired product-current year	3,372
Revision to prior year expense estimate	(1,925)
Deductions	(3,349)
Balance December 31, 2007	$ 6,036

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

During the years ended December 31, 2007, 2006 and 2005, Noven had the following transactions with Novogyne (in thousands):

	2007	2006	2005
Revenues:			
Trade product	$ 18,576	$ 17,013	$ 17,787
Sample product and other	3,849	2,701	2,123
Royalties	7,458	6,845	6,444
	$ 29,883	$ 26,559	$ 26,354
Reimbursed expenses:			
Services	$ 21,771	$ 20,926	$ 20,768
Product specific marketing expenses	7,403	7,850	6,945
Reimbursed expenses	$ 29,174	$ 28,776	$ 27,713

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As of December 31, 2007 and 2006, the Accounts Receivable Novogyne, net is as follows (in thousands):

	2007	2006
Sales of product	$ 4,600	$ 3,795
Services provided by Noven	3,710	3,057
Royalty	1,694	1,714
Deferred profit on Novogyne inventory and other	(1,321)	(873)
	$ 8,683	$ 7,693

7. GOODWILL AND INTANGIBLE ASSETS:

The carrying amount of goodwill is $14.7 million at December 31, 2007, all of which relates to Noven s August 2007 acquisition of JDS.

Noven s intangible assets at December 31, 2007 are detailed in the table below (amounts in thousands):

	Gross carrying amount	Accumulated amortization	Net Carrying Amount	Amortization period (in years)
Product intangibles	$ 42,332	$ (4,122)	$ 38,210	6 - 14
Non-competition agreements	530	(82)	448	2-3
Favorable lease	227	(112)	115	10 months
	$ 43,089	$ (4,316)	$ 38,773	

All intangible assets above, with the exception of Noven patent development costs totaling approximately $1.9 million in net carrying amount at December 31, 2007, were acquired on the Closing Date as part of the JDS acquisition. As of December 31, 2006 Noven s intangible assets consisted of patent development costs of $4.4 million with accumulated amortization of $2.0 million, resulting in a net carrying amount of $2.4 million. Amortization expense, which was $2.3 million, $0.5 million and $0.4 million for 2007, 2006 and 2005, respectively, has been calculated on the following bases for each of the intangible assets in the above table:

Intellectual property amortization of $2.1 million, $0.5 million and $0.4 million for 2007, 2006 and 2005, respectively, is based on the shorter of the period in which the economic benefit is expected to be realized or their remaining legal lives and is included in cost of products sold.

Non-competition agreements are amortized on a straight-line basis and are included in selling, general and administrative expenses. Amortization expense related to these agreements totaled $0.1 million for 2007.

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Favorable lease amortization is based on escalating lease payments on a straight-line basis and is included in selling, general and administrative expenses. Amortization expense related to this lease totaled $0.1 million for 2007.

Noven estimates that the future annual amortization costs for each of the five years through 2012, for intangible assets held at December 31, 2007 are as follows (amounts in thousands):

	Years Ending December 31,				
	2008	2009	2010	2011	2012
Cost of goods sold:					
Intellectual property	$ 4,095	$ 4,012	$ 3,965	$ 3,904	$ 3,888
Selling, general and administrative:					
Non-competition agreements	221	171	55		
Favorable lease	115				
	336	171	55		
Total amortization costs	$ 4,431	$ 4,183	$ 4,020	$ 3,904	$ 3,888

8. OTHER ACCRUED LIABILITIES:

Other accrued liabilities consist of the following (amounts in thousands):

	December 31,	
	2007	2006
Income taxes payable	$ 2,414	$ 204
Accrued medicaid and other rebates	4,065	
Accrued market withdrawal costs	3,300	
Allowance for product returns	1,875	426
Other accrued liabilities	3,616	1,544
Total other accrued liabilities	$ 15,270	$ 2,174

9. OPERATING AND CAPITAL LEASES:

Noven has various operating and capital leases related to its computers and equipment. Noven also leases office space and other warehouse space 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 was 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

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of the leased space as determined under the Lease. Noven improved the leased space in order to prepare it for its intended use during 2005. The landlord was responsible for up to approximately $0.9 million of leasehold improvements, which were fully paid in 2005. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements were 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 three years ended December 31, 2007.

In addition, as part of the JDS acquisition in August 2007, Noven assumed the operating lease of 8,700 square feet of office space that JDS used for their operations in New York, New York. This lease expires in September 2010 and the lease payment is $0.4 million for 2008.

Lease expense under operating leases, including rent expense related to both leases described above, totaled approximately $1.5 million, $1.2 million and $1.1 million for the years ended December 31, 2007, 2006 and 2005, respectively.

The future minimum rental payments required under noncancelable operating and capital leases as of December 31, 2007 are as follows (in thousands):

	Operating Leases	Capital Leases
2008	$ 1,432	$ 200
2009	1,491	171
2010	1,293	8
2011	961	8
2012	964	8
Thereafter	1,887	9
Total lease obligation	$ 8,028	404
Less: portion representing interest		(45)
Capital lease obligation		359
Less: current portion		(171)
Capital lease obligation, net of current portion		$ 188

10. 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

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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 other non-current liabilities in the accompanying consolidated balance sheets. 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 consolidated balance sheets and are reported at cash surrender value, which was approximately $0.5 million and $0.2 million as of December 31, 2007 and 2006, respectively. The balance of the deferred compensation liability totaled $0.6 million and $0.2 million at December 31, 2007 and 2006, respectively.

11. STOCKHOLDERS EQUITY:

Noven established the 1999 Long-term Incentive Plan (the 1999 Plan) on June 8, 1999. The 1999 Plan as amended in May 2004 and May 2007 provides for the granting of incentive and non-qualified stock options, stock awards (including restricted common stock), and other permitted awards to selected individuals for up to 6,268,848 shares. 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 common 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 of the Board of Directors, 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 cannot 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 cannot 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 shares of Noven s common stock). At December 31, 2007, there were 2,263,720 stock options and 1,247,128 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. Effective January 1, 2006, Noven adopted SFAS No. 123(R), which requires compensation expense associated with equity awards to be recognized in Noven s consolidated statements of operations, rather than as historically presented as a pro forma footnote disclosure in Noven s consolidated financial statements.

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Noven granted 26,244 and 34,344 shares of restricted common stock to its non-employee directors in May 2007 and 2006, respectively. The grants fall under the definition of nonvested shares under SFAS 123(R). The shares vest over each director s one-year service period at the end of each calendar quarter beginning with the end of the second quarter. As the shares vest, those shares that have been deferred by non-employee directors under Noven s deferred compensation plan are transferred into a rabbi trust maintained by Noven. In accordance with EITF No. 97-14, Accounting for Compensation Arrangements Where Amounts Earned are Held in a Rabbi Trust and Invested , the deferred shares were recorded at their fair value and classified as common stock held in trust. Since the deferral relates to Noven common stock, an offsetting amount was recorded as deferred compensation obligation in the stockholders equity section of the consolidated balance sheets. As of December 31, 2007 and 2006, there were a total of 48,300 and 21,465 shares of common stock in the rabbi trust, respectively.

On August 14, 2007, Noven granted 8,998 shares of restricted common stock to the former JDS CEO for joining Noven s Board of Directors in connection with the Merger. The shares vested immediately upon grant and were charged to operations in 2007. Also on August 14, 2007, Noven granted 44,297 SSARs as consideration for a non-competition agreement with the same former executive of JDS in connection with the Merger.

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

	Years Ended December 31,					
	2007		2006		2005	
	Stock Options/ SSARs	Weighted Average Exercise Price	Stock Options	Weighted Average Exercise Price	Stock Options	Weighted Average Exercise Price
Outstanding at beginning of year	3,275	$ 19.26	4,004	$ 17.23	3,739	$ 17.69
Granted	907	14.66	411	22.49	557	14.25
Exercised	(162)	15.76	(1,045)	12.77	(137)	9.52
Canceled or expired	(509)	24.65	(95)	18.86	(155)	24.44
Outstanding at end of year	3,511	16.83	3,275	19.26	4,004	17.23
Exercisable at end of year	2,098	17.67	2,136	20.97	2,871	19.14
Shares of common stock reserved	4,729		3,428		4,504	

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The following tables summarize information concerning outstanding and exercisable options/SSARs at December 31, 2007 (options/SSARs and aggregate intrinsic value in thousands):

Stock Options/SSARs Outstanding

Range of Exercise Prices	Number Outstanding at Year End	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 9.08 - $ 13.12	626	2.2	$ 11.54	$ 1,464
13.68 - 19.66	1,802	4.9	14.92	75
20.56 - 24.17	1,037	4.1	22.66	
31.31 - 36.24	46	0.1	31.87	
	3,511	4.1	16.83	$ 1,539

Stock Options/SSARs Exercisable

Range of Exercise Prices	Number Exercisable at Year End	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 9.08 - $ 13.12	522	$ 11.76	$ 1,105
13.68 - 19.66	738	15.69	34
20.56 - 24.17	792	22.59	
31.31 - 36.24	46	31.87	
	2,098	17.67	$ 1,139

The weighted average remaining life of exercisable options/SSARs was 2.8 years as of December 31, 2007. The total fair value of equity grants that vested in each of the years ended December 31, 2007, 2006 and 2005 were $3.6 million, $3.3 million and $21.2 million, respectively. The year ended December 31, 2005 included the acceleration of vesting of stock options with a fair value of $10.1 million, net of applicable taxes, which reduced future compensation expense by that amount. As of December 31, 2007, approximately 3,299,000 outstanding options/SSARs are ultimately expected to vest (including those already vested). Such options have a weighted average exercise price of $16.91, an aggregate intrinsic value of $1,466,000 and weighted average remaining life of 4.0 years as of December 31, 2007.

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The following table summarizes information concerning Noven s restricted common stock at December 31, 2007 (shares in thousands):

	2007	
	Restricted Common Shares	Weighted Average Grant-Date Fair Value
Nonvested, December 31, 2006	8	$17.47
Granted	35	21.28
Vested	(37)	20.12
Nonvested, December 31, 2007	6	$ 22.86

On January 2, 2008, 50,000 shares of restricted stock units with a fair value of approximately $0.7 million were awarded to the former Chief Executive Officer as part of a separation agreement. Although the expense of this award was included in the 2007 consolidated statement of operations, the shares are not reflected as outstanding as of December 31, 2007 as they were granted subsequent to December 31, 2007. The obligation to issue such shares, totaling $0.7 million, is included in other non-current liabilites.

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. On March 18, 2008, Noven s Board of Directors approved an amendment to the Stockholder Rights Plan (as amended, the Plan). The amendment increased the stock ownership threshold that would cause rights issued under the Plan to become exercisable from 15% of shares outstanding to 20% of shares 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 20% 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 20% 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, unless extended, 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 20% 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 existence of the Stockholder Rights Plan could make it more difficult for a third party to acquire a majority of Noven s common stock in a transaction that does not have the support of Noven s Board of Directors.

12. SHARE REPURCHASE PROGRAM:

In the September 2007, Noven s Board of Directors authorized a share repurchase program under which Noven may acquire up to $25.0 million of its common stock. As of December 31, 2007, Noven had repurchased 322,345 shares of its common stock at an aggregate price of approximately $5.1 million. These shares remained in the treasury as of December 31, 2007.

13. 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 $658,000, $656,000 and $397,000 to the 401(k) Plan for the years ended December 31, 2007, 2006 and 2005, respectively.

14. INCOME TAXES:

The provision (benefit) for income taxes for the years ended December 31, 2007, 2006 and 2005 consists of (in thousands):

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	2007	2006	2005
Current income taxes:			
Federal	$ 24,312	$ 7,123	$ 2,347
State	3,414	1,154	367
	27,726	8,277	2,714
Deferred income tax (benefit) expense:			
Federal	(51,174)	(241)	2,291
State	(1,427)	(94)	275
	(52,601)	(335)	2,566
Provision (benefit) for income taxes	$ (24,875)	$ 7,942	$ 5,280

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):

	2007	2006
Deferred income tax assets:		
Deferred license revenue	$ 18,761	$ 6,234
Joint venture interest	3,417	3,451
Inventory adjustments and reserves	3,241	2,153
Deferred profit on sales to Novogyne	498	334
Deferred rent credit	393	433
Non-qualified stock options	2,463	712
Accrued expenses and sales allowances	3,416	355
Basis differences in fixed and intangible assets	37,064	
Other	964	230
Valuation allowance	(3,200)	
Total deferred income tax assets	67,017	13,902
Deferred income tax liabilities:		
Basis difference in fixed assets	(1,350)	(1,194)
Net deferred income tax asset	$ 65,667	$ 12,708

At December 31, 2007 and 2006, net deferred tax assets were $65.7 million and $12.7 million, respectively. The increase primarily arises from the immediate expensing of $100.2 million of IPR&D acquired from JDS which is deductible for tax purposes over 15 years. This temporary difference increased Noven s deferred tax assets by approximately $35.4 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics (formerly known as JDS) files separate state income tax returns in states where it has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. Noven expects that Noven Therapeutics will incur taxable losses in the next few years due to future expected clinical trial expenditures related

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to product development. These expected taxable losses create negative evidence, indicating the need for a valuation allowance at December 31, 2007. Noven recorded a valuation allowance of $3.2 million during the year ended December 31, 2007, due to uncertainties in realizing these state deferred tax assets based on Noven s projection of future state taxable income. If Noven determines, based on future Noven Therapeutics profitability that these state deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

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, 2007, 2006 and 2005, Noven credited $0.5 million, $3.6 million and $0.3 million, respectively, to additional paid-in capital related to the excess tax benefits from the exercise of stock options. The $0.5 million tax benefit credited to additional paid-in-capital in 2007 includes $0.4 million of excess tax benefits classified as cash provided by financing activities in the accompanying consolidated statement of cash flows.

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

	Years Ended December 31,					
	2007		2006		2005	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$ (24,588)	(35.0)	$ 8,375	35.0	$ 5,338	35.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	(2,336)	(3.3)	690	2.9	323	2.1
Non-taxable interest income	(1,486)	(2.1)	(1,323)	(5.5)	(385)	(2.5)
Non-deductible incentive stock option compensation expense	146	0.2	228	0.9		
Extraterritorial income exclusion					122	0.8
Research and development expenditures credit	(167)	(0.2)			(141)	(0.9)
Increase in state tax contingency accruals	544	0.7				
Increase in valuation allowance	3,200	4.5				
Cash surrender value of life insurance	(100)	(0.1)				
Other	(88)	(0.1)	(28)	(0.1)	23	0.1
Income tax (benefit) expense	$ (24,875)	(35.4)	$ 7,942	33.2	$ 5,280	34.6

Upon adoption of FIN 48, and as a result of the recognition and measurement of Noven s tax positions as of January 1, 2007, Noven recognized a charge of approximately $0.5 million to

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the January 1, 2007 retained earnings balance. The gross amount of unrecognized tax benefits as of the date of adoption, January 1, 2007, was $0.9 million. If the $0.9 million is ultimately recognized, approximately $0.6 million would affect the effective tax rate due to approximately $0.3 million in related federal tax benefit. As of December 31, 2007, the gross amount of unrecognized tax benefits was approximately $1.4 million. If the $1.4 million is ultimately recognized, approximately $0.9 million would affect the effective tax rate due to approximately $0.5 million in related federal tax benefit. Interest and penalties related to income taxes are classified as a component of income tax expense. Noven had approximately $0.2 million and $0.1 million accrued at January 1, 2007 for the payment of such interest and penalties, respectively. Noven had approximately $0.3 million and $0.2 million accrued for the payment of interest and penalties at December 31, 2007, respectively. Noven does not expect the gross amount of unrecognized tax benefits to significantly increase or decrease within 12 months after December 31, 2007. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance as of January 1, 2007	$ 909
Additions for tax positions related to the current year	324
Additions for tax positions of prior years	138
Balance as of December 31, 2007	$ 1,371

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. Federal tax returns for years 2004 2006 remain open and subject to examination by the Internal Revenue Service. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes, and Noven s filings with those states remain open for audit, inclusively, for the years 2003 2006. Noven is not aware of any examinations currently taking place related to its income taxes in any jurisdiction. It is possible that examinations may be initiated by any jurisdiction where Noven operates, or where it can be determined that Noven operates, the results of which may increase Noven s income tax liabilities or decrease the amount of deferred tax assets and may also materially change the amount of unrecognized income tax benefits for tax positions taken.

15. SEGMENT AND CUSTOMER DATA:

With the addition of Noven Therapeutics, Noven now operates in two segments distinguished along product categories: (i) Noven Transdermals, which currently engages in the research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products; and (ii) Noven Therapeutics, which currently engages in the development, marketing and sales of pharmaceutical products.

Prior to the Noven Therapeutics acquisition, Noven operated exclusively in the Transdermals segment. Following the acquisition, in accordance with SFAS No. 131, Noven began to separately report information for the Therapeutics segment. Noven evaluates segment performance based on segment contribution which consists of segment gross margin less direct research and development expenses, less direct selling expenses plus (in the case of

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Transdermals) the equity in earnings of Novogyne. Corporate general and administrative expenses, interest income and the immediate expensing of acquired IPR&D have not been allocated to operating segments. The accounting policies of the operating segments are the same as those described in Note 2 Summary of Significant Accounting Policies.

Noven s results by segment are presented in the following table. There are no inter-segment revenues. The results of the Therapeutics segment are from the date of acquisition (August 14, 2007) through December 31, 2007. Prior year comparative data is provided for the Transdermals segment (in thousands):

	Years Ended December 31,		
	2007	2006	2005
Transdermals Segment:			
Net product revenues	$ 56,223	$ 48,326	$ 40,451
License and contract revenues	17,725	12,363	12,081
Net revenues	73,948	60,689	52,532
Cost of products sold	(37,871)	(36,508)	(34,047)
Research and development	(12,473)	(11,454)	(13,215)
Selling and marketing	(1,059)	(967)	(563)
Equity in earnings of Novogyne	35,850	28,632	24,655
Transdermals contribution	58,395	40,392	29,362
Therapeutics Segment:			
Net product revenues	9,213		
Cost of sales	(3,146)		
Research and development	(1,505)		
Selling and marketing	(8,101)		
Therapeutics contribution	(3,539)		
Total Contribution	54,856	40,392	29,362
Unallocated Expenses:			
Acquired IPR&D	(100,150)		
General and administrative	(30,411)	(20,734)	(16,352)
Interest income, net	5,454	4,272	2,242
Income (loss) before income taxes	$ (70,251)	$ 23,930	$ 15,252

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Depreciation and amortization included within segment contributions for each year was as follows (in thousands):

	Years Ended December 31,		
	2007	2006	2005
Transdermals	$ 4,775	$ 4,544	$ 3,162
Therapeutics	1,905		
Total	$ 6,680	$ 4,544	$ 3,162

Segment assets consisted of the following as of December 31, 2007 and 2006 (in thousands):

	2007	2006
Transdermals:		
Receivables and inventory	$ 21,629	$ 46,382
Property, plant and equipment, net	36,038	37,010
Investment in Novogyne	24,310	23,296
Intangible assets	1,935	2,317
Total Transdermals	83,912	109,005
Therapeutics:		
Receivables and inventory	6,146	
Property, plant and equipment, net	175	
Intangible assets, net	36,838	
Goodwill	14,734	
Total Therapeutics	57,893	
Not allocated to segments:		
Cash and investments	68,373	153,599
Deferred tax assets	65,667	12,708
Prepaids, deposits and other assets	10,853	6,053
	144,893	172,360
Total Assets	$ 286,698	$ 281,365

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There were no intercompany sales or transactions. The following table presents information about Noven s revenues by geographic area (in thousands):

	Years Ended December 31,		
	2007	2006	2005
United States	$ 66,864	$ 43,628	$ 34,546
Other countries	16,297	17,061	17,986
Net revenues	$ 83,161	$ 60,689	$ 52,532

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

	Years Ended December 31,		
	2007	2006	2005
Novogyne	$ 29,883	$ 26,559	$ 26,354
Shire	27,392	14,556	
Novartis Pharma/Novartis	15,070	15,287	16,955
Endo	79	303	6,682
Other	10,737	3,984	2,541
Net revenues	$ 83,161	$ 60,689	$ 52,532

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

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Year ended December 31, 2007[1]					
Net revenues	$ 19,315	$ 18,839	$ 21,815	$ 23,192	$ 83,161
Gross profit (product revenues less cost of products sold)	6,679	5,748	6,879	5,113	24,419
Income (loss) from operations	1,501	631	(103,668)	(10,019)	(111,555)
Equity in earnings of Novogyne[2]	4,903	9,174	10,948	10,825	35,850
Net income (loss)	$ 5,036	$ 7,576	$ (59,037)	$ 1,049	$ (45,376)
Basic earnings (loss) per share	$ 0.20	$ 0.31	$ (2.38)	$ 0.04	$ (1.84)
Diluted earnings (loss) per share	$ 0.20	$ 0.30	$ (2.38)	$ 0.04	$ (1.84)
Year ended December 31, 2006					
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 from operations	(4,168)	(2,868)	(1,870)	(68)	(8,974)
Equity in earnings of Novogyne[2]	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
Year ended December 31, 2005					
Net revenues[3]	$ 11,736	$ 11,771	$ 12,240	$ 16,785	$ 52,532
Gross profit (loss) (product revenues less cost of products sold)[3]	4,256	5,124	(4,969)	1,993	6,404
(Loss) income from operations	(1,086)	(687)	(11,239)	1,367	(11,645)
Equity in earnings of Novogyne[2]	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

See notes on following page.

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[1] Our results for 2007 included: (i) a one-time $100.2 million charge recorded in the 2007 third quarter for the JDS acquisition purchase price allocated to in-process research and development; (ii) a $3.3 million charge recorded in the 2007 third quarter related to payments to Shire in connection with the voluntary market withdrawals of a portion of Daytrana product; (iii) an aggregate $3.3 million charge recorded in the 2007 fourth quarter related to separation arrangements with certain executive officers; and (iv) results of operations of JDS from the date of acquisition (August 14, 2007) through December 31, 2007.

[2] 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.

[3] 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 revenues, which were 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.

[4] Quarterly and year-to-date computations of per share amounts are made independently. Therefore, the sum of per share amounts for the quarters may not agree with per share amounts for the year.

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17. COMMITMENTS AND CONTINGENCIES:

HT STUDIES:

Since 2002, several studies, including the Women s Health Initiative (WHI) study performed by the National Institutes of Health (NIH) and a study performed by the National Cancer Institute (NCI), have identified increased risks from the use of HT, including increased risks of invasive breast cancer, ovarian cancer, stroke, heart attacks and blood clots. As a result of the findings from these 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 HT products in the aggregate. Researchers continue to analyze data from 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 HT products are not being used in the study, the market for our HT 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 s products have been named in lawsuits filed against Noven, Novogyne and Novartis.

SUPPLY AGREEMENTS:

Noven s supply agreement with Novogyne for Vivelle® and Vivelle-Dot® patches expired in January 2003. While the parties have continued to operate in accordance with certain of the supply agreement s pricing terms, there is no assurance that the parties will continue to do so. 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. Since Noven appoints two members of Novogyne s Management Committee, both Novartis and Noven must agree on Novogyne s supplier. In connection with a transition to Vivelle-Dot®, effective December 2006, Noven ceased supplying Vivelle® product to Novogyne.

Noven and Shire are also parties to a long-term supply agreement under which we manufacture and supply Daytrana to Shire at a fixed price. In 2007, our product sales of Daytrana to Shire were $13.4 million. The supply 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.

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.

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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. One additional lawsuit was filed subsequent to December 31, 2007.

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

Novartis has advised Noven that Novartis is currently named as a defendant in at least 26 additional lawsuits that include approximately 27 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, 2007 was $10.0 million. Novogyne has established reserves in the amount of $9.0 million with an offsetting insurance recovery of $6.8 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, 2007.

In June 2007, Johnson-Matthey Inc. filed a complaint in the United States District Court, Eastern District of Texas against Noven alleging that Noven was infringing one of its patents through its manufacture and sale of Daytrana. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. Noven intends to vigorously defend this lawsuit. In July 2007, Johnson-Matthey added Shire as a defendant to this lawsuit after Shire filed a declaratory judgment against Johnson-Matthey in the United States District Court, Eastern District of Pennsylvania. In August 2007, Noven filed a motion for a transfer of venue of the case to the United States District Court, Eastern District of Pennsylvania.

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 condition, results of operations or cash flows.

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FDA WARNING LETTER:

In January 2008, Noven received a warning letter from the FDA in connection with the FDA s July 2007 inspection of its manufacturing facilities in Miami, Florida. An FDA warning letter is intended to provide notice to a company of violations of the laws administered by the FDA and to elicit voluntary corrective action.

In the warning letter, the FDA cites Current Good Manufacturing Practice deficiencies related to Noven s Daytrana patch and the: (i) peel force specifications for removal of Daytrana s release liner; and (ii) data supporting the peel force characteristics of Daytrana s enhanced release liner throughout the product s shelf life. The warning letter, which is posted at the FDA s website at www.fda.gov, requested additional information and analysis related to the cited deficiencies and instructed Noven to take prompt action to address the FDA s concerns. Noven submitted a response to the warning letter on January 30, 2008. Noven cannot assure that the response will be acceptable to the FDA or satisfactorily address the FDA s concerns.

Noven expects to incur increased quality assurance costs related to its continued efforts to address the issues raised by the FDA in the July 2007 Form 483 and January 2008 warning letter. A significant portion of these costs will be allocated to Daytrana , which will negatively affect the gross margin on sales of this product in 2008. Unless the violations identified in the warning letter are corrected, the FDA may withhold approval of marketing applications relating to products manufactured at Noven s Miami, Florida facility. Failure to take effective corrective actions can result in FDA enforcement action such as monetary fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any enforcement action by the FDA would have a material adverse effect on Noven, including the potential loss of Daytrana sales, potential loss of sales of other products, the potential inability to achieve the remaining Daytrana sales milestone, the potential for litigation related to this matter, harm to Noven s reputation and various costs associated with the foregoing.

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.

NOVEN THERAPEUTICS COMMITMENTS:

Noven Therapeutics has certain commitments and contingencies related to contractual arrangements, primarily related to milestone payments for development, FDA submission, FDA approval and commercial sales of products under development. As of December 31, 2007, Noven Therapeutics was responsible for $23.5 million in such contingent milestones, which may be payable over the next three to five years. As of December 31, 2007, $11.5 million of these milestones were reflected as liabilities in Noven s consolidated balance sheet. See Note 5 Contract and License Agreements for additional information.

EMPLOYMENT AGREEMENT AND BONUS PLAN:

Noven has a formula bonus plan that includes company and individual performance goals. Noven incurred $3.4 million, $3.1 million and $3.6 million of bonus expenses in 2007, 2006, and

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2005, respectively, under this plan. Under the plan, a fixed percentage of each eligible employee s base salary is established 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 or her target award. An employee s non-financial goals are then considered in determining his or her final bonus award. In 2007 and 2006 Noven s performance was less than the company s performance targets, and in accordance with the plan formula the bonus awards to employees were less than their initial target awards. In 2005, 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. In addition Noven Therapeutics incurred $0.2 million and $0.8 million of performance and retention bonuses, respectively, in 2007.

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Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying balance sheets and the related statements of operations, members capital and cash flows present fairly, in all material respects, the financial position of Vivelle Ventures LLC at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Florham Park, NJ
March 7, 2008

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Balance Sheets
December 31, 2007 and 2006

	2007	2006
Assets		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation (Note 6)	$ 30,120,429	$ 23,688,751
Due from affiliate Novartis Pharmaceuticals Canada	826,885	1,116,767
Finished goods inventory (net of reserves of $16,293 and $13,225 as of December 31, 2007 and 2006)	5,237,638	4,069,226
Insurance receivable (Note 7)	287,758	
Other current assets	521,072	572,733
Total current assets	36,993,782	29,447,477
Noncurrent assets		
Insurance receivable (Note 7)	6,484,118	7,299,241
Intangible assets (net of amortization of $41,711,388 and $35,531,923 as of December 31, 2007 and 2006) (Note 3)	20,083,257	26,262,722
Total noncurrent assets	26,567,375	33,561,963
Total assets	$ 63,561,157	$ 63,009,440
Liabilities and Members Capital		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc. (Note 6)	$ 10,004,646	$ 8,566,562
Accrued liabilities	170,048	376,877
Product liability reserve (Note 7)	8,976,093	9,629,241
Allowance for returns (Note 4)	6,035,609	7,937,905
Total current liabilities	25,186,396	26,510,585
Commitments and contingencies (Note 7)		
Members capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	5,516,852	3,640,946
Total members capital	38,374,761	36,498,855
Total liabilities and members capital	$ 63,561,157	$ 63,009,440

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Operations
Years Ended December 31, 2007, 2006 and 2005

	2007	2006	2005
Net sales			
Third parties	$ 145,814,777	$ 128,973,730	$ 119,331,180
Novartis Pharmaceuticals Canada, Inc.	2,173,124	2,969,045	2,226,126
	147,987,901	131,942,775	121,557,306
Cost of sales			
Sales to third parties	16,662,926	15,886,720	15,148,711
Sales to Novartis Pharmaceuticals Canada, Inc.	902,738	1,237,620	923,604
Noven royalties	7,458,470	6,845,122	6,444,033
Amortization of license/marketing rights	6,179,465	6,179,465	6,179,465
	31,203,599	30,148,927	28,695,813
Gross profit	116,784,302	101,793,848	92,861,493
Operating expenses			
Sales and marketing expenses	34,976,800	32,928,299	31,657,682
Administrative expenses	3,221,335	3,494,020	3,377,400
Product liability (income)/expenses, net of insurance receivable	(114,269)	896,053	533,947
Income from operations	78,700,436	64,475,476	57,292,464
Other income			
Interest income	1,145,116	841,564	461,294
Net income	$ 79,845,552	$ 65,317,040	$ 57,753,758

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Members Capital
Years Ended December 31, 2007, 2006 and 2005

	Total
Members capital at January 1, 2005	$ 42,286,191
Net income	57,753,758
Distributions to Novartis	(35,583,169)
Distributions to Noven	(27,644,951)
Members capital at December 31, 2005	36,811,829
Net income	65,317,040
Distributions to Novartis	(37,050,205)
Distributions to Noven	(28,579,809)
Members capital at December 31, 2006	36,498,855
Net income	79,845,552
Distributions to Novartis	(43,133,607)
Distributions to Noven	(34,836,039)
Members capital at December 31, 2007	$ 38,374,761

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Cash Flows
Years Ended December 31, 2007, 2006 and 2005

	2007	2006	2005
Cash flows from operating activities			
Net income	$ 79,845,552	$ 65,317,040	$ 57,753,758
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	3,068	(18,752)	31,977
Changes in assets and liabilities			
(Increase) decrease in due from affiliate Novartis Pharmaceuticals Corporation	(6,431,678)	(5,737,117)	5,179,494
Decrease (increase) in due from affiliate Novartis Pharmaceuticals Canada, Inc.	289,882	(1,116,767)	
(Increase) decrease in finished goods inventory	(1,171,480)	3,260	(1,908,275)
Decrease (increase) in other current assets	51,661	(265,258)	(16,976)
Decrease (increase) in insurance receivable	527,365	(3,788,373)	(2,810,868)
Increase (decrease) in due to affiliate Noven Pharmaceuticals, Inc.	1,438,084	(1,220,745)	(895,425)
(Decrease) increase in accrued liabilities	(206,829)	(177,465)	(628,594)
(Decrease) increase in product liability reserve	(653,148)	4,684,426	3,344,815
(Decrease) increase in allowance for returns	(1,902,296)	1,770,300	(3,001,251)
Net cash provided by operating activities	77,969,646	65,630,014	63,228,120
Cash flows from financing activities			
Distributions to members (Note 5)	(77,969,646)	(65,630,014)	(63,228,120)
Net cash used in financing activities	(77,969,646)	(65,630,014)	(63,228,120)
Net change in cash			
Cash and cash equivalents			
Beginning of year			
End of year	$	$	$

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

1. Organization and Business

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

On January 2, 2008, the Company formally communicated the discontinuation of the sales and distribution of all strengths of Vivelle to its customers. Consequently, there will be minimal, if any, future sales of this product on a go-forward basis.

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.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

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 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, 2007, 2006, and 2005 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 chargebacks 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 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 s products.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

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

	Years Ended December 31,		
	2007	**2006**	**2005**
Gross sales	$ 169,173,682	$ 151,931,653	$ 134,675,279
Sales returns	$ 1,446,688	$ 5,732,390	$ 935,912
Managed health care rebates	13,226,491	10,117,301	8,018,050
Cash discounts	3,387,440	3,041,805	2,690,058
Medicaid and Medicare Part D rebates including prescription drug savings cards	1,636,510	980,498	938,423
Chargebacks	1,297,620	1,032,093	969,492
Other discounts	2,364,156	2,053,836	1,792,164
Total sales allowances	23,358,905	22,957,923	15,344,099
Net sales to third parties	$ 145,814,777	$ 128,973,730	$ 119,331,180

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 $143,844, $126,128, and $146,322 for 2007, 2006, and 2005, 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.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

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 $41,711,388 and $35,531,923 as of December 31, 2007 and 2006. 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, 2007 and 2006. Further evaluations may be required if additional declines in the market for CombiPatch® develop due to the HT studies or other factors.

4. Allowance for Returns

The methodology used by the Company to estimate product returns related to expired product for Vivelle-Dot® and CombiPatch® 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.

On January 2, 2008, the Company formally communicated to its customers that it would discontinue the sales and distribution of all strengths of Vivelle. Consequently, there will be minimal, if any, future sales of the product after such date. The Company does not expect this announcement to have a material effect on the allowance for Vivelle returns.

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Vivelle Ventures LLC
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Years Ended December 31, 2007, 2006 and 2005

The activity for the allowances for returns for the years ended December 31, 2007 and 2006 is as follows:

Balance January 1, 2006	$ 6,167,605
Current year provision	4,342,016
Prior year adjustment	1,390,374
Deduction returns processed	(3,962,090)
Balance December 31, 2006	7,937,905
Current year provision	3,371,702
Prior year adjustment	(1,925,014)
Deduction returns processed	(3,348,984)
Balance December 31, 2007	$ 6,035,609

5. Operating Agreement

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

Management Committee

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

Allocation of Net Income and Loss

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

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

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

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Vivelle Ventures LLC
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Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

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

Lastly, all remaining net income attributable to Vivelle® and all other net income, including net income attributable to Vivelle-Dot® and CombiPatch®, are to be allocated to the members in proportion to their respective percentage interests.

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

Distributions

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

Distributable funds are payable to the Members quarterly or as determined by the Management Committee. Distributions are made to the Members based on taxable income. Commencing in 2002, the state of New Jersey enacted legislation that requires the Company to remit estimated tax payments on behalf of its New Jersey nonresident owners, Novartis and Noven. Included in the 2007 distributions to Novartis and Noven of $43,133,607 and $34,836,039, respectively, are payments related to New Jersey state taxes of $3,533,947 and $5,991,899, respectively. The $5,991,899 of state tax payments include $2,791,899 related to 2006 and $3,200,000 of 2007 estimated taxes. 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 to New Jersey for state taxes of $2,076,945 and $1,458,356, 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. There have been no events in 2007 that would trigger a dissolution of the Company.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

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 in the world (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot® subject to the terms of the prior arrangement between Noven and Novartis, and the Company s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement.

6. Transactions with Affiliates

Services

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

Novartis is responsible for providing the following services:

Shipment of the products, fulfillment of product orders, inventory control and distribution, processing of invoices and cash management.

Management of the overall marketing and sales program for the products in the managed care sector of the market, including but not limited to all corporate, institutional and government accounts.

Customer service support and assistance for the products.

Regulatory affairs support and assistance for the products.

Bookkeeping and accounting, administrative functions relating to the distribution and sale of the products, and assistance with tax matters, insurance coverage and treasury services.

Manage and defend the Company in various litigation matters.

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, 2007, 2006 and 2005, Novartis charged the Company $3,173,158, $2,989,159 and $3,133,136, respectively, for these services.

Bookkeeping, Accounting, Treasury and Legal

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 $30,120,429 and $23,688,751, as of December 31, 2007 and 2006, 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, 2007, 2006 and 2005 at an average annual rate of 5.48%, 5.25% and 3.6%, respectively. During these periods, interest of $1,145,116, $841,564 and $461,294, respectively, was earned and is reflected in the amount Due from affiliate Novartis Pharmaceuticals Corporation.

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Vivelle Ventures LLC
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Notes to Financial Statements
Years Ended December 31, 2007, 2006 and 2005

The Members have agreed that Novartis is responsible for managing the receivables balances and Novartis bears the risk of the balances not being recovered in full. However, the Company records receivables for sales to Novartis Pharmaceuticals Canada, Inc. and retains the risk related to these balances. These receivables are reflected in the amount Due from affiliate Novartis Pharmaceuticals Canada.

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

	Years Ended December 31,	
	2007	2006
Balance at the beginning of the period	$ 23,688,751	$ 17,951,634
Net sales third parties (excluding returns)	147,261,465	134,706,120
Sales returns processed	(3,348,984)	(3,962,090)
Interest income on cash balances	1,145,116	841,564
Distributions by Novartis to members	(77,969,646)	(65,630,014)
Payments made by Novartis to Noven for marketing services, inventory purchases and royalties	(57,770,647)	(56,699,396)
Disbursements made by Novartis on behalf of the Company	(2,175,474)	(2,382,186)
Novartis service charges	(3,173,158)	(2,989,159)
Cash received from Novartis Pharmaceuticals Canada	2,463,006	1,852,278
Total	$ 30,120,429	$ 23,688,751

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, 2007, 2006 and 2005, Noven charged the Company $21,771,373, $20,926,359, and $20,768,126, 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 for services as well as marketing and promotion materials during the years ended December 31, 2007, 2006 and 2005 were $11,251,496, $10,551,108, and $8,970,238, respectively.

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.

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Vivelle Ventures LLC
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Years Ended December 31, 2007, 2006 and 2005

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 $7,458,470, $6,845,122 and $6,444,033 for the years ended December 31, 2007, 2006 and 2005, respectively.

Inventory Purchases

Vivelle®, Vivelle-Dot® and CombiPatch® are manufactured by Noven and sold to the Company at an agreed upon price. Noven ceased the manufacturing of Vivelle for the Company at the end of 2006. During the years ended December 31, 2007, 2006 and 2005, the Company purchased products from Noven in the amounts of $18,575,309, $17,012,690 and $17,787,186, respectively.

In January 2008, Noven received a warning letter from the FDA in connection with the FDA s July 2007 inspection of its manufacturing facilities in Miami, Florida. An FDA warning letter is intended to provide notice to a company of violations of the laws administered by the FDA and to elicit voluntary corrective action.

In the warning letter, the FDA cites Current Good Manufacturing Practice deficiencies related to one of Noven s products that is unrelated to the Company. The warning letter requested additional information and analysis related to the cited deficiencies and instructed Noven to take prompt action to address the FDA s concerns. Noven submitted a response to the warning letter on January 30, 2008. Noven cannot assure that the response will be acceptable to the FDA or satisfactorily address the FDA s concerns.

Unless the violations identified in the warning letter are corrected, the FDA may withhold approval of marketing applications relating to products manufactured at Noven s Miami, Florida facility. Failure to take effective corrective actions can result in FDA enforcement action such as monetary fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any enforcement action by the FDA may have a material adverse effect on the Company if Noven is unable to supply product to the Company, which would lead to loss of sales, harm to the Company s reputation and various costs associated with the foregoing.

Research and Development

Noven assumes responsibility for research and development costs associated with the development of Vivelle®, Vivelle-Dot®, CombiPatch® and all future generation products (Note 7).

Due to Affiliate Noven Pharmaceuticals, Inc.

The following represents the amounts payable to Noven related to:

	December 31,	
	2007	**2006**
Purchases of inventory	$ 4,599,843	$ 3,795,409
Services provided by Noven	3,710,352	3,056,883
Royalties	1,694,451	1,714,270
	$ 10,004,646	$ 8,566,562

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7. Commitments and Contingencies

Litigation, Claims and Assessments

As of December 31, 2007, there have been 46 lawsuits that include 60 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 46 lawsuits filed, 14 lawsuits have been dismissed and 1 lawsuit has been settled for a nominal amount. For the remaining 31 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 25 lawsuits only name Novartis. Further one additional lawsuit was filed between December 31, 2007 and the date of these financials.

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 has established reserves in the amount of $8,976,093 and $9,629,241 as of December 31, 2007 and 2006, respectively, for expected defense and settlement expenses as well as for estimated future cases alleging use of the Company s products prior to the label change. 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. Costs to defend these cases are incurred by Novartis and will be charged to the Company.

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 $6,771,876 and $7,299,241 as of December 31, 2007 and 2006, respectively. Currently, although the Company s insurance carrier has sent the Company a reservation of rights letter for each claim, the coverage is not in dispute. The Company plans to pursue having these claims treated as a serial loss for insurance purposes. As of December 31, 2007, the Company s insurance carrier has not determined these claims to be a serial loss for insurance purposes. Therefore, the Company has expensed 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 and recovery has not been deemed probable at this time.

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For the year ended December 31, 2004 the Company had a claims-made insurance policy with a $50,000 deductible per claim and a $10,000,000 aggregate limit, including defense costs. The Company also purchased the optional 5 Year Extended Reporting Period Endorsement which permits coverage for an occurrence prior to the expiration of the current policy term (January 1, 2005) to be reported under the 2004 policy during the next five years, as long as policy limits have not been eroded by prior claims.

The Company, Novartis and Noven intend to vigorously defend themselves in the HT litigation. Several HT litigation cases have been tried in court over the past several years with varying results. While the majority of the Company s HT cases remain in the early stages, the anticipated date for commencement of trial is approaching. 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, exceeds the $10,000,000 aggregate limit under the policy, or the Company is unable to recover payments under its product liability insurance policy.

For the period January 1, 2005 through December 31, 2007, the Company had a claims-made insurance policy 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.

Recently Enacted State Laws

The Company is subject to a variety of recently enacted state laws which require prescription drug manufacturers to submit periodic reports summarizing costs associated with advertising and promoting prescription drugs to residents of the respective states, economic benefits made available to healthcare providers, and costs of employees and contractors involved in certain marketing activities. The Company failed to meet the reporting deadline in two jurisdictions in 2007. Both jurisdictions have the right to assess civil penalties, and recover costs and attorney s fees incurred to enforce their respective statutes. While it is reasonably possible the Company may be assessed fines for failing to comply with the reporting deadlines, the Company is unable to estimate, with reasonable certainty, the possible loss, or range of loss, if any, at this time. The Company does not expect the resolution of this matter to have a significant adverse impact on its financial statements.

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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 generally continued to operate in accordance with the supply agreement s pricing mechanism. 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. In connection with a transition to the Company s product, Vivelle-Dot, effective December 2006, Noven ceased supplying Vivelle product to the Company.

HT Studies

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

Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage, including a new five-year study aimed at determining whether ET used by women aged 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 results of operations, or the Company s ability to recover the carrying value of the CombiPatch® intangible asset.

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8. Concentrations of Credit Risk

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 36%, 39% and 20% in 2007, 38%, 37% and 20% in 2006, and 35%, 37% and 21% in 2005.