NOVEN PHARMACEUTICALS INC
Form 10-K
March 13, 2009

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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, 2008

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. 144 th 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 o No þ
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 the definitions 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 $266 million (computed by reference to the price at which the common equity was last sold on June 30, 2008, the last business day of the registrant s most recently completed second fiscal quarter).

As of March 2, 2009, there were 24,913,418 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of the registrant s Proxy Statement for its 2009 Annual Meeting of Stockholders

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NOVEN PHARMACEUTICALS, INC.
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for the year ended December 31, 2008
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Trademark Information: DOT Matrix® and DentiPatch® are registered trademarks of Noven Pharmaceuticals, Inc.; Lithobid®, Pexeva® and Stavzor® are registered trademarks, and Mesafem is a trademark 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; Menoaid® is a registered trademark of Purapharm International; Femiest® is a registered trademark of sanofi-aventis in Japan; Daytrana® is a registered trademark of Shire Pharmaceuticals Ireland Limited; 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 registered trademark of Wyeth Laboratories or affiliates; and Vyvanse® is a registered 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 21 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, manufacturing, licensing, marketing and sale of prescription pharmaceutical products. Our business is focused in three principal areas: (i) Noven Transdermals, our transdermal drug delivery segment; (ii) Novogyne Pharmaceuticals (Novogyne) our women s health joint venture with Novartis Pharmaceuticals Corporation (Novartis); and (iii) Noven Therapeutics, our specialty pharmaceutical segment. Each of these principal areas is more fully discussed below.

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 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 CombiPatch® and seeking to

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expand the range of products offered by the Novogyne sales force; and (iii) leveraging the marketing and sales infrastructure and industry expertise of Noven Therapeutics with specialty pharmaceutical products, and with complementary products that we will seek to develop or acquire, and possible strategic collaborations all with the goal of establishing Noven as a leading, high growth specialty pharmaceutical company. We regularly review our corporate strategies to evaluate their suitability and effectiveness in light of evolving business, industry, market and other conditions.

Noven operates in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, our women s health joint venture with Novartis in which we own a 49% equity interest and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products. Historically, Novogyne was viewed as a component of the Noven Transdermals unit because the joint venture s primary activity involves the marketing and sale in the United States and Canada of patches manufactured by Noven Transdermals. In the fourth quarter of 2008, as a result of management and organizational changes throughout 2008, Noven revised its presentation of reportable segments to reflect the joint venture as a reportable unit distinct from the manufacturing and licensing activities of Noven Transdermals. This view is consistent with the manner in which information is reported for management decision making. See Note 17 Segment and Customer Data in our Notes to Consolidated Financial Statements for Noven s segment financial reporting.

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 website address is www.noven.com.

Noven Transdermals

Our Noven Transdermals segment is engaged in the manufacturing, licensing and sale 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 primarily 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.

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Patches incorporating our patented 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. DOT Matrix® is a highly efficient class of diffusion-based drug-in-adhesive patch technology, patented through 2014, that can often deliver more drug through a smaller patch area than competitive patches without using irritating skin permeation enhancers and without compromising adhesion. This patented blend of silicone adhesive, acrylic adhesive and drug 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 DOT Matrix® and other transdermal technologies enable 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.

Novogyne Pharmaceuticals

Our HT products are marketed and sold in the United States through Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) (Novogyne), a joint venture that we established with Novartis in 1998 to market and sell women s prescription healthcare products. These products include our transdermal hormone therapy product delivery systems marketed under the brand names Vivelle-Dot® and CombiPatch®. We hold a 49% equity interest in Novogyne, and Novartis holds the remaining 51% equity interest.

Novogyne s sales and marketing efforts have helped Vivelle-Dot® to become the most prescribed product in the transdermal estrogen therapy (ET) patch category, with a 61% share of monthly total prescriptions written in the United States as of December 31, 2008. In connection with a transition to our advanced Vivelle-Dot® product, we ceased manufacturing 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 Vivelle-Dot® and CombiPatch® to Novogyne, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of Vivelle-Dot® and CombiPatch®. 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. 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.

We account for our investment in Novogyne under the equity method of accounting and report our share of Novogyne s earnings as Equity in earnings of Novogyne on our Consolidated Statements of Operations. We defer the recognition of 49% of our profit on products sold to Novogyne until the products are sold by Novogyne to third party customers. Under the terms of the joint venture agreements, 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%. In 2008, 2007 and 2006, our share of Novogyne s income was $45.6 million, $35.9 million and $28.6 million,

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respectively, representing 48.9%, 48.6% and 48.4%, respectively, of Novogyne s income after Novartis preferred returns for each of those years. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions which are based upon a contractual formula. 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 2008, 2007 and 2006, we received $42.0 million, $28.8 million and $26.4 million, respectively, in distributions from Novogyne, which accounted for a substantial portion of our net operating cash flows for these periods. We expect that for the next several years a substantial portion of our earnings and cash flows will be generated through our interest in Novogyne.

Novogyne is managed by a committee (the Management Committee) comprised of five members, three of whom are appointed by Novartis and two of whom are appointed by Noven. Noven s Executive Vice President is a Management Committee member and serves as President of Novogyne. 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. 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 original license agreement with Novartis for Noven s transdermal estrogen patches, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances. The joint venture will also dissolve upon the expiration of the original license agreement with Novartis for Noven s transdermal estrogen patches, as described below under Commercialized Products Hormone Therapy -Vivelle-Dot®/Estradot®.

The joint venture agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire the other party s entire interest in the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If we are the purchaser, then we must also pay an additional amount equal to the net present value of Novartis preferred return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return.

Noven Therapeutics

In August 2007, we acquired Noven Therapeutics, which now comprises our specialty pharmaceutical operations. Noven Therapeutics currently markets and sells three branded prescription psychiatry products:

Stavzor®, a valproic acid delayed release product utilizing a proprietary enteric-coated soft gelatin capsule delivery system. In July 2008, the FDA granted final approval for the product, which is indicated for use 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. Stavzor® was commercially launched in August 2008.

Pexeva®, a selective serotonin re-uptake inhibitor (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 indicated for the maintenance of bipolar disorder and the treatment of related manic episodes.

In addition, we are advancing the development of Mesafem, a non-hormonal therapy in Phase 2 clinical studies for the treatment of vasomotor symptoms associated with menopause. We will seek to leverage Noven Therapeutics marketing and sales infrastructure with complementary products that we will 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®/ Menoaid®	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	Currently undergoing Phase 1 study
Testosterone Patch	Hypoactive Sexual Desire Disorder and other indications	Developmental	Partner s NDA withdrawn in December 2004
		Noven Therapeutics	
Stavzor®	Bipolar disorder, migraine therapy and epilepsy	Commercialized	FDA-approved
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
Mesafem		Developmental	

	Vasomotor symptoms (hot flashes)		Currently undergoing Phase 2 study
	Transmucosal		
DentiPatch®	Dental pain associated with certain dental procedures	Commercialized	FDA-approved

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Commercialized Products

Hormone Therapy

Overview

Our menopausal HT products consist of:

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

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

Our HT products are indicated for menopausal symptoms. 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. 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.

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, although the lowest dosage strength is approved only for prevention of osteoporosis.

In the United States and Canada, Noven has granted exclusive marketing rights for Vivelle-Dot® (and any follow-on transdermal estrogen patches) to Novogyne pursuant to a license agreement with Novartis that was subsequently assigned to Novogyne. The license agreement provides for Noven s receipt of royalty payments based upon sales. The license agreement is currently scheduled to expire in August 2014, co-terminus with the expiration of the patents for Vivelle-Dot®. The term of the license agreement will be extended for any follow-on transdermal estrogen patches subject to the agreement. Upon expiration, Novartis retains a perpetual, royalty-free, non-exclusive license to the product. 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 multiple international markets.

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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.

CombiPatch®/Estalis®/Menoaid®

We developed the first combination transdermal HT system approved for marketing by the FDA (marketed as CombiPatch®, Estalis® and Menoaid®), a combination patch containing estradiol and norethindrone acetate, a progestin.

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

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. We sell the product to Novogyne at an agreed-upon price pursuant to a supply agreement.

The HT Product Market

We currently derive a significant portion of our revenues and substantially all of our net income from our HT products. Our total HT-related net revenues were $52.3 million, $45.6 million and $42.7 million for 2008, 2007 and 2006, respectively, which represented 48%, 55% and 70%, respectively, of our net 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 prescription trends for our products, see Management s Discussion and Analysis of Financial Condition and Results of Operations Executive Summary. 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 HT products have been named in lawsuits filed against

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Noven, Novogyne and Novartis. See Note 19 Commitments and Contingencies Litigation, Claims and Assessments, in our Notes to Consolidated Financial Statements.

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 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. We believe that, among other advantages Daytrana® possesses as compared to certain oral ADHD medications, 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 milestone payments to us of up to $150.0 million, all of which have been received. We are currently deferring and recognizing these milestone payments as license revenues on a straight-line basis, beginning on the date each was achieved through the first quarter of 2013, which is our current best estimate of the end of the useful economic life of the product.

Because we have received all milestone payments under the license agreement, Shire s obligations under the license agreement to promote Daytrana® and refrain from selling any other methylphenidate product have expired. Noven and Shire are also parties to a supply agreement under which we manufacture and supply Daytrana® to Shire at a fixed price. In 2008, our product sales of Daytrana® to Shire were $10.8 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 sales of Daytrana® to Shire would be adversely affected.

Noven and Shire have received reports from some consumers concerning the difficulty of removing the release liner from certain Daytrana® patches. In the first quarter of 2007 we, together with Shire, implemented enhancements to the Daytrana® release liner. In July 2007 we received a list of observations on Form 483 from the FDA following an inspection of our manufacturing facilities and the majority of these

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observations related to the Daytrana® patch and difficulties in removing the product s release liner, including certain product lots that utilized an enhanced release liner. In January 2008, we received a warning letter from the FDA citing deficiencies in the peel force specifications for Daytrana®.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve.

During 2007 and 2008, Shire initiated voluntary market recalls (two in each year) of a portion of the Daytrana® product on the market primarily in response to feedback from patients and caregivers who continued to experience difficulty removing the release liner from some Daytrana® patches. In February 2008, we paid Shire $3.3 million related to the 2007 recalls and in November 2008, we paid Shire $3.7 million related to the 2008 recalls.

In the fourth quarter of 2008, we implemented new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, we cannot assure that our testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls. A more detailed discussion of the Daytrana® peel force issue and the associated financial impact can be found under the heading Certain Items that May Affect Historical or Future Comparability Daytrana® in Management s Discussion and Analysis of Financial Condition and Results of Operations.

We believe we have identified the root cause of the peel force issue. Noven is testing manufacturing solutions designed to address the peel force issue. Implementation of the solutions being tested will require prior agreement from the FDA. Subject to FDA review and agreement, Noven s current plan calls for shipments to Shire in the third or fourth quarter of 2009. We cannot assure that the FDA will approve the solutions being tested on a timely basis or at all. Noven s warning letter remains under review by the FDA.

Psychiatry Products

Our commercialized prescription psychiatry products consist of Stavzor®, a valproic acid delayed release product, Pexeva®, an SSRI antidepressant and Lithobid®, an extended release lithium product, all of which are oral products. We market and sell these products through the Psychiatry/CNS marketing and sales infrastructure of Noven Therapeutics. These products are manufactured by third parties and supplied to us under manufacturing and supply agreements.

Stavzor®

In July 2008, the FDA granted final approval for Stavzor®, which was commercially launched in August 2008. Stavzor® is a valproic acid delayed release product that utilizes a proprietary enteric-coated soft gelatin capsule delivery system. This product is indicated for use 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. Stavzor® competes with Abbott Laboratories Depakote® product and its generic equivalents.

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Noven Therapeutics is party to a development, license and supply agreement with Banner Pharmacaps Inc. (Banner), the exclusive manufacturer and supplier of the product. In consideration for certain license and development rights granted by Banner under the agreement, we are obligated to make certain potential future payments, including escalating royalties on future sales.

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.

Noven Therapeutics acquired Pexeva® from Synthon Pharmaceuticals, Inc. (Synthon) in November 2005. In this transaction, Noven Therapeutics 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 possible future contingent milestone payments of up to $11.5 million in the event sales of Pexeva® or any other products based on the same compound as is used in Pexeva® achieve specified levels. We accrued for these contingent payments at the time of closing of the Noven Therapeutics transaction. We became obligated to pay $6.5 million of such milestones based on sales of Pexeva® in 2007 and 2008. In 2008, we recognized $5.0 million in operating income as a result of the reversal of the remaining accrued liability upon our determination that the achievement of the remainder of the contingent milestone was no longer probable based on projected sales of Pexeva®. However, we remain contingently liable for the $5.0 million payment if annual net sales of a future product utilizing the same compound as is used in Pexeva® achieves $30.0 million or more through 2017.

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.

Noven Therapeutics acquired Lithobid® from Solvay Pharmaceuticals, Inc. (Solvay) in August 2004. In this transaction, Noven Therapeutics purchased certain assets related to Lithobid® including the NDA, intellectual property (including trademarks) and certain finished goods inventory. ANI Pharmaceuticals, Inc. (ANI) manufactures Lithobid® under a manufacturing and supply agreement with Noven Therapeutics.

Transmucosal Product

DentiPatch®, approved in 1996 and launched in 1997, was the first FDA-approved oral transmucosal patch. Sales of DentiPatch® are not material to our consolidated results of operations and we intend to discontinue the product once current inventory is exhausted, which we expect to occur during 2009.

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Products Under Development

Research and Development

Transdermal Products

Our long-term prospects are dependent upon the successful development and commercialization of new products. Noven s research and development program investigates and seeks to identify compounds that can be delivered transdermally which we believe may have substantial clinical utility and 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.

Mesafem

As part of the Noven Therapeutics acquisition, we acquired a women s health product called Mesafem that, if successfully developed and 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 market exclusivity under the Hatch-Waxman Act. As of the date of this report, Mesafem is in Phase 2 clinical studies.

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 product under development by Wyeth Pharmaceuticals for VMS. We estimate that 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.

Lithium QD and Stavzor® ER

Following an internal review and rationalization of projects in our drug development pipeline, we discontinued development of our Lithium QD and Stavzor® ER projects in November 2008.

For the years ended December 31, 2008, 2007 and 2006, our research and development expense was $15.5 million, $14.0 million (excluding acquired in-process research and development) and $11.5 million, respectively. To bring Mesafem to market, we plan to increase our research and development expense significantly over the next several years. 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

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timing of clinical studies and whether we are or a third party is 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 fluctuations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations.

Transdermal Product Development Collaborations

Amphetamine Transdermal System

On November 5, 2008, we entered into a letter agreement (the Termination Agreement) with Shire terminating our agreements with Shire for the development of an amphetamine patch for ADHD. Under the Termination Agreement, rights to the developmental amphetamine patch were returned to us and we intend to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if we elect to commercialize a product that incorporates intellectual property arising from the development project with Shire. As a result of the termination of this project with Shire, we recognized $7.2 million of previously deferred license and contract revenues in the fourth quarter of 2008.

Transdermal System for HSDD

In April 2003, we established a collaboration with Procter & Gamble Pharmaceuticals, Inc. (P&GP) relating to the development and commercialization of prescription transdermal patches for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in women. The products under development explore follow-on product opportunities for Intrinsa®, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore sexual desire in menopausal women diagnosed with HSDD.

In August 2008, we entered into global license and supply agreements with P&GP, which supersede and replace the prior development letter agreement entered into between Noven and P&GP in April 2003. Under the agreements, we granted P&GP an exclusive worldwide license to our low-dose testosterone patch for use by women for HSDD and other indications, as well as potential next-generation patches, and P&GP granted us exclusive supplier rights with respect to such licensed products. If the testosterone patch is ultimately approved and commercially launched, we would receive royalties and manufacturing fees under the agreements. We may also receive additional contingent development and sales milestone payments related to the licensed products. The royalty payments are to be determined based on a percentage of P&GP s quarterly sales of the licensed products. The milestone payments are contingent upon the achievement of certain sales milestones. Pursuant to the agreements, P&GP will fund any clinical development costs and will be responsible for any regulatory filings and marketing applications associated with any licensed products developed under the agreements.

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

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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 have, as well as greater experience in developing and commercializing pharmaceutical products. 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.

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, 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. Shire currently markets products for the treatment of ADHD that compete with Daytrana®. We cannot assure that Shire will continue to market Daytrana® aggressively or effectively.

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 Pharmaceuticals, Inc. and others, including Novartis, Novartis Pharma and their affiliates. We expect increased competition in the HT market as new and innovative products continue to be introduced in this field, including products using alternative delivery systems such as gels, creams and 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.

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 there is no approved generic equivalent to Pexeva®, 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 re-uptake inhibitors, substance P antagonists and CRF receptor antagonists.

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In the market for the treatment of manic episodes associated with bipolar disorder, 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.

Also in the market for the treatment of manic episodes associated with bipolar disorder, as well as monotherapy and adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches, Stavzor® competes against, among others, Abbott Laboratories Depakote® product and its generic equivalents.

Dependence on Licensees and the Novogyne Joint Venture

During 2008, 27%, 34%, and 13% of our revenues were attributable to Novogyne, Shire and Novartis Pharma (and its affiliates), respectively, and our profitability has been significantly dependent on our equity in Novogyne s earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novogyne, Shire and Novartis Pharma and other collaboration partners, as well as fees, amortization of previously received 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 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. 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.

Manufacturing

We 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. 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.

Some raw materials essential to our transdermal business are readily available from multiple sources. Certain raw materials and components used in manufacturing 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

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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 manufacturing and supply agreements, we rely upon third party manufacturers to manufacture and supply us with Stavzor®, Pexeva® and Lithobid®. 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.

As discussed above under ADHD Therapy Daytrana®, we are working to address certain manufacturing-related issues associated with the Daytrana® product.

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 comprised of approximately 70 sales representatives and related marketing and sales infrastructure in support of our Stavzor®, Pexeva® and Lithobid® products.

On behalf of our Novogyne joint venture, we maintain and manage an approximately 120-person women s health sales force and related sales and marketing infrastructure in support of our Vivelle-Dot® and CombiPatch® products. In general, Noven s costs associated with these employees and substantially all of our sales and marketing activities conducted on behalf of Novogyne are reimbursed by Novogyne. 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 Mesafem is ultimately 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 our

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transdermal products in development 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.

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 350 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 150 pending patent applications worldwide. As a result of changes in United States patent law under the General Agreement on Tariffs and Trade and the accompanying agreement on Trade-Related Aspects of Intellectual Property Law, 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 in Note 19 Commitments and Contingencies Litigation, Claims and Assessments in the Notes to our Consolidated Financial Statements, 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.

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, manufacturing, labeling, marketing and sale of pharmaceutical products, and the possession and use of controlled substances. We devote significant time, effort and expense to address the extensive government regulations applicable to our business.

The marketing of pharmaceutical products requires the approval of the FDA in the United States. The FDA has established regulations, guidelines and safety standards that apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of pharmaceutical products. The process of obtaining FDA approval for a new product may take several years or more and is likely to involve the expenditure of substantial resources. The steps required before a product can be produced and marketed for human use typically include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Application (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials that demonstrate reasonable assurance of the safety and efficacy of the product; (iv) submission to the FDA of an NDA; and (v) review and approval of the NDA by the FDA. Approval of a product by the FDA does not guarantee the product s safety or efficacy.

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.

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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.

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

Human clinical trials are typically conducted in three sequential phases prior to FDA approval, but the phases may overlap. Phase 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 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

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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 or additional studies involving patients located in their countries.

Manufacturing facilities are subject to periodic inspections for compliance with the FDA s good manufacturing practices regulations and each domestic drug manufacturing facility must be registered with the FDA. Most foreign regulatory authorities have similar regulations. In complying with standards set forth in these regulations, we must expend significant time, money and effort in the area of quality assurance to ensure full technical compliance. Facilities handling controlled substances, such as ours, also must be licensed by the DEA, and are subject to more extensive regulatory requirements than those facilities not licensed to handle controlled substances. We also require approval of the DEA to obtain and possess controlled substances, including methylphenidate and amphetamine. We produce transdermal drug delivery products, and our third party manufacturers produce Stavzor®, 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.

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 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. 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. We have a compliance program designed to monitor and assist us in our compliance with these rules and regulations.

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,

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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 and two Form 483 s primarily related to Daytrana®.

Backlog

Our backlog for Noven Transdermals totaled $0.4 million as of March 2, 2009, substantially all of which is expected to be filled during 2009. Our backlog for Noven Transdermals totaled $2.9 million as of March 7, 2008, all of which was filled during 2008. We did not have a backlog for Noven Therapeutics in 2008 or 2007.

Employees

As of March 2, 2009, we had approximately 610 employees, approximately 261 of which were engaged in manufacturing, process development, quality assurance and quality control, 223 in marketing and sales, 81 in general administration, 31 in research and development and 14 in clinical research and regulatory affairs. Included in these numbers are 85 individuals who became employees of Noven as a result of the Noven Therapeutics acquisition in August 2007. Also included are approximately 148 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 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 (Forms 3, 4 and 5) filed by our officers, directors and other reporting persons under Section 16 of the Securities Exchange Act of 1934. Our 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 could adversely affect us or that may cause our results to differ materially from the forward-looking statements contained in this report or otherwise made by or on our behalf. The risks and uncertainties described below are not necessarily listed in order of probability or 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 could 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.

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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 the warning letter, which is posted on the FDA s website, the FDA cited 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.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve.

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 adequately address the issues raised by the FDA in the warning letter as well as the production and other issues involving Daytrana® could result in additional regulatory action, including fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any enforcement action would be expected to have a material adverse effect on us, including 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, manufacturing 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 third quarter of 2007, Shire initiated two voluntary recalls 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 certain Daytrana® patches. We paid Shire $3.3 million in February 2008 related to the 2007 recalls. These costs were charged to operations in 2007. In 2008, we recorded additional expenses of

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approximately $3.7 million related to two additional voluntary recalls by Shire in 2008 of four lots of Daytrana® and certain previously-manufactured lots that would not have met the newly implemented release testing standard and are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life. In addition, during 2008, we established a reserve of $3.8 million related to these affected lots. We do expect that there will be an additional voluntary withdrawal/recall of some Daytrana® lots due to the peel force issue. While we believe the $3.8 million reserve is adequate for the costs of such withdrawal/recall, we cannot assure that our costs related to this issue will not exceed the amount reserved.

We do not carry 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.

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. 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® has been and may continue to be negatively affected by the peel force issues, the FDA warning letter, Shire s 2007 and 2008 voluntary market recalls and other factors, although we have taken steps to implement 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.

If we cannot develop, license or acquire new products and commercialize them on a timely basis, including Mesafem, our financial condition and results of operations could be adversely affected.

Our long-term strategy is dependent upon the successful development and commercialization of new products. 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. Mesafem, our

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women s health product under development for the treatment of vasomotor symptoms associated with menopause, is in Phase 2 clinical trials. We cannot assure that Phase 2 clinical trials for Mesafem will be successful, and even if they are successful, whether Phase 3 clinical trials will ultimately be successful.

Furthermore, the potential success of a new pharmaceutical product is subject to many risks which could have a material adverse effect on our business, financial condition and results of operations, including, but not limited to: (i) 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; (ii) the unproven safety and efficacy of products under development; (iii) the difficulty of predicting FDA approval, including the timing of approval and that approval may not be granted at all; (iv) 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; (v) the impact of competitive products, pricing and managed care and formulary status; (vi) the possibility that any product launch may be delayed or that product acceptance and demand may be less than anticipated; (vii) the possibility that patent applications may not result in issued patents and that issued patents may not be enforceable or could be invalidated; (viii) 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 (ix) the potential negative impact of competitive responses to our sales, marketing and strategic efforts.

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, which may be costly and may not provide the expected benefits.

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, the technology being found to infringe upon the intellectual property rights of a third party or the acquired product or technology achieving less market acceptance or commercial success than anticipated. 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 due to current economic conditions and extremely tight credit markets. Acquisition efforts, whether consummated or not, can consume significant management attention and require substantial expenditures, which could detract from our other programs.

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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 risky, 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, as well as publicity surrounding COX-2 inhibitors and certain antidepressants, it is possible that healthcare regulators, including the FDA and the Drug Safety Oversight Board, could delay the approval of certain 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, limitations or monitoring after approval. 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 assure the future commercial success of the currently marketed products or that Mesafem, an important developmental product acquired in the acquisition, will receive marketing approval or achieve commercial success. 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 preceding risk factors.

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 plan to increase our research and development expenses significantly over the next several years as we advance the development of Mesafem. We cannot assure the future success of this product or whether we will be able to recover our initial and ongoing investment in Noven Therapeutics and its products.

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

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of those products among healthy postmenopausal women. For example, total prescriptions dispensed in the HT market in the United States declined by 56% from 2002 (the year of publication of the results of the WHI study) to 2008. 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 the use of HT products. 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 transdermal 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.

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

Our 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 would likely 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 agreements, 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 the establishment and maintenance of internal controls 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

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Noven. Further, any material errors in Novogyne s financial statements could lead to a restatement of Novogyne s financial statements, which would likely require us to restate our financial statements.

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®, 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 Vyvanse®, an amphetamine pro drug for the treatment of ADHD which competes with our Daytrana® product. Shire dedicated substantial resources to the promotion of this product. 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. Our agreements with Shire required Shire to use commercial efforts to market Daytrana® until payment of all milestone payments, but Shire has no obligation to continue marketing Daytrana® thereafter. We have already received all such milestone payments. 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.

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 manufacturing 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.

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We face scale-up risks in manufacturing new transdermal products in commercial quantities.

Inefficiencies and other scale-up problems can occur in the process of manufacturing new products in commercial quantities. If we do not adequately and timely scale-up our manufacturing processes for new 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 cause our collaboration partners, if permitted under our agreements, to rely 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. If we experience manufacturing difficulties such as quality problems, yield deficiencies or similar issues, our overall manufacturing costs may be higher than anticipated.

We rely on 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 Stavzor®, Pexeva®, and Lithobid®, which are 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, but not limited to the following: (i) inconsistent production yields and difficulties in scaling production to commercial and validation sizes; (ii) difficulties obtaining raw materials; (iii) equipment failures, potential facility catastrophes and plant time scheduling issues; (iv) quality control and assurance issues; and (v) lack of regulatory compliance with the FDA s, or other agencies , regulations and specifications.

Furthermore, we have no control over whether the third party manufacturers breach their agreements with us or whether they 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

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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 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 manufacturing 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, manufacturing, 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.

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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 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 have either enacted, or are considering enacting, 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. 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 the Noven Therapeutics acquisition, 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. If we are not 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

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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.

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 generally fixed and is determined in accordance with the terms of our supply agreement with Shire. Consequently, our margin on sales of Daytrana® is determined by our production costs and yields. If our production yields decrease or our costs of production for Daytrana® increase, our profitability will be adversely impacted. In particular, we have incurred and expect to incur in 2009 increased quality assurance costs related to the Daytrana® peel force issue and our efforts to address the concerns raised by the FDA in the two Form 483 s and the warning letter. Our ability to produce Daytrana® and continue to improve the gross sales margin is contingent on, among other things, resolving the peel force issue and receiving a sufficient supply of the active methylphenidate ingredient from Shire, as well as sufficient quota of the controlled substance from the DEA. 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 have. As a result, they may succeed before us in developing competing technologies or obtaining regulatory 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. We may also face competition for our Vivelle-Dot® product from generic equivalents, which could erode market demand for the product, exerting pricing pressure on our product and consequently adversely impact our results of operations and financial condition. The ADHD market is highly competitive, and our

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competitors include our partner 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 & Johnson, Novartis, GlaxoSmithKline, Bristol-Myers Squibb, Abbott Laboratories, Celltech, and Lilly.

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 could 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 have. Stavzor® competes against, among others, Abbott Laboratories Depakote® product and its generic equivalents. 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 near expiration; 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 generic marketing exclusivity period of 180 days 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 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 and Spain (without the benefit of government reimbursement) and in a number of smaller European countries.

Our quarterly operating results are subject to significant fluctuations.

In 2008, 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 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 sales and marketing efforts for Daytrana®. Our earnings may also fluctuate because of, among other things, fluctuations in research and development expenses resulting from the timing of clinical trials and our efforts to bring Mesafem 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 Noven Therapeutics 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 difference. Novogyne recorded the acquisition of the CombiPatch® product marketing rights at cost and tests this asset for impairment when factors indicate there may be a possible impairment. In addition, intangible assets in the form of patent development costs and goodwill from the acquisition of Noven Therapeutics comprise a significant portion of our total assets. Goodwill is tested for impairment annually in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying value of goodwill may not be recoverable. If after testing

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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 previously invested a portion of our cash in auction rate securities, which subjects us to liquidity and investment risk. We could be required to record additional impairment charges if the fair value of these investments continues to decline.

At December 31, 2008, we held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of $16.0 million and $15.5 million, respectively. 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. 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. As a result of failed auctions, these investments now pay interest at a rate defined by the governing documents or indenture.

In 2008, we liquidated a substantial portion of our auction rate securities at par and recorded unrealized losses of $0.5 million to reduce the remaining investments to fair value, which impairments were determined to be other-than-temporary and recognized in our 2008 Consolidated Statement of Operations.

Our auction rate security investments are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. We do not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. We believe our investments are of high credit quality, as all are investment grade and the majority are rated AA or higher. In assessing whether declines in fair value are temporary in nature or other-than-temporary, management considers a variety of factors, including our recent history of liquidating similar instruments at par value, the length of time and extent to which the fair value has been less than par, the financial condition of the issuer of the investment and management s intent and ability to retain the investments for a sufficient period to allow for any anticipated recovery in fair value. In the fourth quarter of 2008, management determined that the $0.5 million unrealized decline in fair value of our auction rate securities was other-than-temporary. We will continue to monitor the market for our auction rate security investments. If management determines in a future period that existing temporary declines or further declines in fair value are other-than-temporary, we will be required to record a charge to operations in the period when such determination is made. As illiquid conditions persist in the auction market for these securities, it may become increasingly more likely that we will need to recognize additional other-than-temporary impairment charges in future periods. Such non-cash impairment charges could materially and adversely affect our consolidated financial condition and results of operations. See Note 5 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 (GAAP). The preparation of financial statements in accordance with GAAP involves making

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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 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 these 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 judgments underlying 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 could be a materially adverse impact on our net revenues and results of operations.

In the pharmaceutical industry, our 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 of our products, except for Stavzor®, for which we do not yet have sufficient sales history to reasonably estimate returns. 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 could be a material impact to our results of operations.

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 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 successfully enforce our patent rights, including our patent rights relating to Pexeva® and Mesafem, our results of operations and financial condition may be adversely impacted.

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Additionally, we cannot assure that our patents or any future patents will prevent third parties 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 in the United States District Court, Eastern District of Texas, against us alleging that we were infringing one of its patents through our manufacturing and sale of Daytrana®. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. In July 2007, Johnson-Matthey added Shire as a defendant in this lawsuit. The parties have commenced formal discovery and the case has been scheduled for trial in late 2009. We intend to vigorously defend this lawsuit, but the outcome cannot ultimately be predicted. See Note 19 Commitments and Contingencies Litigation, Claims and Assessments, in the Notes to our Consolidated Financial Statements.

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 successfully 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

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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 results of operations.

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 pre-determined contract prices and discounts. 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 who participate in the Medicaid program 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 and rebates paid 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 results of operations.

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, the new presidential administration has indicated that it will advocate and seek reforms to the current health care system. Additionally, some parties have advocated for the re-importation of prescription drugs from Canada and other countries for resale 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, Novogyne and Novartis have been named as defendants in cases in which a plaintiff alleges personal injury from the use of HT products which we manufacture and Novogyne distributes. 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. Novartis has indicated that it will seek

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indemnification from us and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and us. 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. In recent years, the cost of product liability insurance 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. As of December 31, 2008, Novogyne s aggregate limit under its claims-made insurance policy was $10.0 million. Novogyne has established reserves in the amount of $9.0 million with an offsetting insurance receivable of $6.7 million for expected defense and settlement expenses as well as for estimated future cases alleging use of Noven s HT products. This accrual represents Novogyne management s best estimate as of December 31, 2008.

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 due to a 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 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.

Our insurance coverage may not be adequate and rising insurance premium costs 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,

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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. We face significant competition in recruiting talented personnel. In the past, our Miami, Florida location, which is an area with relatively few pharmaceutical companies, 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 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

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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 Novogyne operating agreement has a buy/sell provision that either we 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 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.

The market price for our common stock is volatile.

The market price for our common stock is volatile. During 2008, our common stock traded as low as $8.57 per share and as high as $14.28 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 securities litigation arising from significant downward movement in our stock price, which could have a material adverse effect on our business and financial results.

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The recent volatility in the financial markets and deteriorating economic conditions could adversely affect us or our partners, customers or suppliers.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Among other risks we face, the current tightening of credit in financial markets may adversely affect our ability to access our credit facility or obtain financing in the future, including, if necessary, to fund a product, technology or business acquisition. In addition, current economic conditions could harm the liquidity or financial position of our partners, customers or suppliers, which could in turn cause such parties to fail to meet their contractual or other obligations to us. Novogyne has currently recorded a product liability insurance receivable in the amount of $6.7 million due from a subsidiary of American International Group (AIG). Although AIG has advised that its commercial insurance subsidiaries remain well-capitalized despite the parent company s recent liquidity issues and diminished financial position, we cannot assure that the insurance carrier will pay the amounts that Novogyne believes are owed under the policy, either due to a change in the carrier s financial condition, a coverage dispute or otherwise.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our headquarters and our 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 used for laboratory, office and administrative purposes. We also lease from Aventis, for $1.00 per year, seven 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 or expiration of our 1992 license agreement with Aventis. This lease includes an option to purchase the leased facilities and property for its depreciated value and subsequent to year-end, we began the process of exercising this option and purchasing the facilities and properties for $1.00, its depreciated value as of December 31, 2008. 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. The lease for the office space can be renewed by us until 2013. The initial lease term for the industrial space 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 five acres of undeveloped 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 Noven Therapeutics acquisition in August 2007, we assumed the operating lease of 8,700 square feet of office space that Noven Therapeutics used for their operations in New York, New York. This lease expires in September 2010.

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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.

See Note 19 Commitments and Contingencies Litigation, Claims and Assessments, in the Notes to our Consolidated Financial Statements for information regarding legal proceedings.

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, 2008.

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 12, 2009. 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.

Peter Brandt. Mr. Brandt, age 51, was appointed to Noven s Board and to the offices of President and Chief Executive Officer in April 2008. From 1981 until 2007, Mr. Brandt served in a number of executive positions at Pfizer, Inc. (pharmaceuticals). He served as Pfizer s President U.S. Pharmaceuticals Operations from August 2006 until January 2007 and as its Senior Vice President U.S. Pharmaceuticals Operations from January 2006 to August 2006. From 2004 to 2006, Mr. Brandt served as President Latin America Operations and as Senior Vice President Worldwide Pharmaceuticals Finance, IT, Planning and Business Development, Pfizer Health Solutions. From 1998 to 2004, he served as Senior Vice President Worldwide Pharmaceuticals Finance, Planning and Business Development and Pfizer Health Solutions.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 43, has been with Noven since November 1998 and, since January 2008, has served as Executive Vice President. From January 2008 to April 2008, he served as Noven s Interim Chief Executive Officer. From May 2005 to January 2008, he served as Noven s Senior Vice President Strategic 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.

Michael D. Price. Mr. Price, age 51, 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

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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.

Steven M. Dinh. Mr. Dinh, age 53, was appointed Vice President and Chief Scientific Officer of Noven in June 2008. From 1997 to 2007, Mr. Dinh served in the dual role of Vice President of Research and Technology Development and Co-Chair Office of the President for Emisphere Technologies. Previously, he served as Chief Scientific Officer and Vice President of Research and Development for Lavipharm Laboratories, where he led research and development efforts in drug delivery and transdermal and cosmetic products. Prior to Lavipharm, he held several senior-level research and development positions focused in transdermal and pharmaceutical research and development for Novartis Pharmaceuticals Corporation and Ciba-Geigy.

Richard P. Gilbert. Mr. Gilbert, age 58, has served Noven as Vice President Operations since December 2004. From January 2000 to November 2004, he served as Vice President, Manufacturing Operations, at ConvaTec (a Bristol-Myers Squibb Company). Prior to ConvaTec, Mr. Gilbert held various senior roles at London International Group, LLC, The Tensar Corporation, and Richmond Technology.

Joel S. Lippman, M.D. Dr. Lippman, age 54, was appointed Vice President Clinical Development and Chief Medical Officer of Noven in July 2008. From 2006 to 2008, he served as an independent consultant to companies in the healthcare industry. From 2000 to 2006, Dr. Lippman served Ethicon, Inc., a Johnson & Johnson company, as Worldwide Vice President Medical Affairs and Chief Medical Officer and as a member of that company s Global Management Board. From 1990 to 2000, he served Ortho-McNeil Pharmaceutical, Inc., also a Johnson & Johnson company, as Vice President Clinical Trials. From 1988 to 1990, he served Wyeth-Ayerst Laboratories in a number of clinical development, medical affairs and related roles.

Anthony Venditti. Mr. Venditti, age 50, was appointed Vice President Marketing & Sales of Noven in June 2008. From 2005 to 2007, he served Novartis Pharmaceuticals Corporation as Vice President and head of Novartis United States Neuroscience division, where he was responsible for marketing, sales and new product operations for the central nervous system (CNS) portfolio in the United States. From 1996 to 2005, he served Novartis in a number of senior executive positions, with responsibility for marketing, sales, business analysis, strategic planning and new product commercialization, including key roles in the launch of several new products.

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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 2, 2009, we had 214 stockholders of record of our Common Stock. We have never declared a cash dividend on our Common Stock and do not anticipate declaring 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, 2008	$12.24	$ 9.45
Third Quarter, 2008	13.31	9.65
Second Quarter, 2008	12.97	8.57
First Quarter, 2008	14.28	8.98
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

Stock Repurchase Program

The following table provides information with respect to our stock repurchases during the fourth quarter of 2008:

	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, 2008 to October 31, 2008				$19,876,238
November 1, 2008 to November 30, 2008				19,876,238
December 1, 2008 to December 31, 2008				19,876,238
Totals				$19,876,238

1 In September 2007, we established 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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Comparison of Five-Year Cumulative Total Return

The following graph and table show the cumulative total return, assuming the investment of $100 on December 31, 2003, 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 graph and 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 declared dividends to our stockholders since our inception and do not plan to declare dividends in the foreseeable future. The following graph and chart are 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.

Noven Pharmaceuticals, Russell 2000 Index and Value Line Value Line Drugs Index*
(Performance Results Through 12/31/08)

	2003	2004	2005	2006	2007	2008
Noven Pharmaceuticals	$100.00	$112.16	$ 99.47	$167.32	$ 91.26	$ 72.32
Russell 2000 Index	$100.00	$117.00	$120.88	$141.43	$137.55	$ 89.68
Value Line Drugs Index	$100.00	$ 99.10	$108.99	$125.53	$136.16	$123.67

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 (amounts in thousands, except per share amounts).

	Years Ended December 31,				
	2008[1,3]	2007[2,3]	2006[3]	2005[4]	2004
Consolidated Statement of Operations Data:					
Net Revenues:					
Product revenues, net	$ 77,627	$ 65,436	$ 48,326	$ 40,451	$ 36,871
License and contract revenues	30,548	17,725	12,363	12,081	9,020
Total net revenues	108,175	83,161	60,689	52,532	45,891
Costs and Expenses:					
Cost of products sold	51,861	41,017	36,508	34,047	20,514
Acquired in-process research and development		100,150			
Research and development	15,527	13,978	11,454	13,215	9,498
Selling and marketing	23,299	9,160	967	563	624
General and administrative	36,796	30,411	20,734	16,352	16,647
Total costs and expenses	127,483	194,716	69,663	64,177	47,283
Reversal of contingent milestone liability	5,000				
Loss from operations	(14,308)	(111,555)	(8,974)	(11,645)	(1,392)
Equity in earnings of Novogyne	45,642	35,850	28,632	24,655	17,641
Interest and other income, net	2,022	5,454	4,272	2,242	999
Loss on auction rate securities	(515)				
Income (loss) before income taxes	32,841	(70,251)	23,930	15,252	17,248
Provision (benefit) for income taxes	11,429	(24,875)	7,942	5,280	6,024
Net income (loss)	$ 21,412	$ (45,376)	$ 15,988	$ 9,972	$ 11,224
Basic earnings (loss) per share	$ 0.87	$ (1.84)	$ 0.67	$ 0.42	$ 0.48
Diluted earnings (loss) per share	$ 0.87	$ (1.84)	$ 0.66	$ 0.42	$ 0.46

Weighted average number of common shares outstanding:					
Basic	24,617	24,728	23,807	23,566	23,332
Diluted	24,729	24,728	24,252	23,981	24,305

Refer to footnotes on the following page.

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	As of December 31,				
	2008[1,3]	2007[2,3]	2006[3]	2005[4]	2004
Consolidated Balance Sheet Data:					
Current Assets:					
Cash and cash equivalents	$ 62,875	$ 13,973	$ 9,144	$ 66,964	$ 93,958
Short-term investments available-for-sale, at fair value	3,650	21,565	144,455	17,900	
Other current assets	47,113	45,565	56,608	34,746	48,763
Non-current Assets:					
Property, plant and equipment, net	34,886	36,213	37,010	34,455	22,587
Investments in auction rate securities	11,810	32,835			
Investment in Novogyne	24,319	24,310	23,296	23,243	26,233
Net deferred income tax asset, non-current portion	65,159	58,053	8,308	6,373	8,239
Intangible assets, net[5]	36,508	38,773	2,317	2,211	2,174
Goodwill[5]	14,407	14,734			
Deposits and other non-current assets	839	677	227	18	21
Total assets	$ 301,566	$ 286,698	$ 281,365	$ 185,910	$ 201,975
Current liabilities	$ 62,994	$ 57,079	$ 29,386	$ 28,488	$ 45,372
Non-current liabilities:					
Long-term obligations, less current portion	27	8,438	279		121
Deferred license and contract revenues, non-current portion	77,112	85,056	74,188	16,053	27,443
Other non-current liabilities	997	1,831	837	748	
Total liabilities	$ 141,130	$ 152,404	$ 104,690	$ 45,289	$ 72,936
Stockholders equity	$ 160,436	$ 134,294	$ 176,675	$ 140,621	$ 129,039

[1] Financial results for 2008 included: (i) the recognition of $7.2 million of previously deferred license and contract revenues as a result of the termination of our agreements with Shire for

the development of an amphetamine patch, (ii) the recognition of $5.0 million in operating income from the reversal of an accrued liability related to a future Pexeva® contingent sales milestone, (iii) $3.7 million of charges associated with the voluntary market withdrawal of a portion of the Daytrana® product by Shire, (iv) a $3.8 million charge related to previously manufactured Daytrana® product at risk of exceeding the product s peel force specification during its shelf life, and (v) a $1.8 million charge related to a patent infringement case.

[2] Financial results for 2007 included: (i) a $100.2 million charge recorded in the 2007 third quarter for the portion of the Noven

Therapeutics acquisition purchase price allocated to in-process research and development; (ii) a $3.3 million charge associated with the voluntary withdrawal of a portion of Daytrana® product by Shire; (iii) a $3.3 million fourth quarter charge related to separation arrangements with certain executive officers; and (iv) results of operations of Noven Therapeutics from the date of acquisition (August 14, 2007) through December 31, 2007.

[3] Financial results for 2008, 2007 and 2006 included $4.8 million, $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.

4 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.

5 Intangible assets, net and goodwill increased in 2007 as a result of the Noven Therapeutics acquisition on August 14, 2007.

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

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

An executive summary of our 2008 consolidated results of operations;

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 2009;

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 2008 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 2008 included a full year of the results of operations of Noven Therapeutics (previously known as JDS Pharmaceuticals), a specialty pharmaceutical company that we acquired on August 14, 2007. Our financial results included the results of operations of Noven Therapeutics beginning on the acquisition date (August 14, 2007). Noven Therapeutics is a specialty pharmaceutical company focused in CNS and women s health indications, with a targeted sales force, three marketed psychiatry products, and a non-hormonal product for vasomotor symptoms in clinical development. The Noven Therapeutics 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 2008 also included: (i) the recognition of $7.2 million of previously deferred license revenues as a result of the termination of our agreements with Shire for the development of an amphetamine patch; (ii) the recognition of $5.0 million in operating income due to the reversal of an accrued liability related to a future Pexeva® contingent sales milestone; (iii) $3.7 million in charges for reimbursements to Shire for voluntary recalls of certain Daytrana® product initiated by Shire in 2008, as well as the establishment of a $3.8 million reserve related to previously-manufactured Daytrana® product at risk of exceeding the product s peel force specification during its shelf life (this aggregate $7.5 million amount is referred to as the 2008 Daytrana® Charges); and (iv) a $1.8 million charge related to a patent infringement case.

Our financial results for 2007 included: (i) a $100.2 million charge for the portion of the Noven Therapeutics purchase price allocated to in-process research and development (the IPR&D Charge); (ii) a $3.3 million charge for reimbursements to Shire for voluntary recalls of certain Daytrana® product (the 2007 Daytrana® Charges); and (iii) an aggregate $3.3 million charge related to separation arrangements associated with the retirement of certain former executive officers.

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Including the impact of these items, we reported net income of $21.4 million ($0.87 diluted earnings per share) for 2008 compared to a net loss of $45.4 million ($1.84 loss per share) for 2007. Our net revenues in 2008 were $108.2 million, an increase of 30% compared to $83.2 million reported in 2007. This increase reflects the recognition of $24.5 million in net revenues associated with Noven Therapeutics, primarily due to our sales of Pexeva® and Lithobid® products as well as increased license and contract revenues, primarily due to the $7.2 million recognized as a result of the termination of certain of our agreements with Shire, as discussed above, in addition to increased amortization of deferred revenue from Daytrana® sales milestone payments. The increase in net revenues was partially offset by a $1.6 million reduction in revenues for 2008, representing a portion of the 2008 Daytrana® Charges.

Gross margin, as a percentage of net product revenues, was 33% in 2008 compared to 37% in 2007. Cost of products sold in 2008 included $1.1 million of the 2008 Daytrana® Charges, $2.8 million of inventory write-offs primarily related to an equipment failure in transdermal manufacturing, as well as increased quality assurance activities and expenses, primarily related to Daytrana® production. Although we implemented new manufacturing processes that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, we expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the active methylphenidate ingredient (AMI) included in destroyed product, unless and until the peel force issue is resolved.

Excluding the $100.2 million IPR&D Charge in 2007, research and development expenses in 2008 increased $1.5 million to $15.5 million compared to 2007. Selling and marketing expenses increased to $23.3 million from $9.2 million in 2007, reflecting a full year of selling and marketing expenses at Noven Therapeutics, including $4.8 million related to Stavzor®, which was commercially launched in August 2008. In 2008, general and administrative expenses increased $6.4 million, or 21%, reflecting $4.8 million of the 2008 Daytrana® Charges (compared to $2.2 million in 2007), a full year of expenses at Noven Therapeutics, and a $1.8 million charge related to a patent infringement case.

We recognized $45.6 million in earnings from Novogyne in 2008, an increase of 27% compared to 2007. Net revenues at Novogyne increased 15% to $169.6 million in 2008, primarily due to increased sales of Vivelle-Dot®. Novogyne s gross margin percentage for 2008 increased slightly to 80%. Novogyne s selling, general and administrative expenses were $37.5 million in 2008, a 2% decrease from 2007. Novogyne s net income for 2008 increased 25% to $99.5 million compared to $79.8 million in the prior year.

At December 31, 2008, we had $62.9 million in cash and cash equivalents and $15.5 million in investments in auction rate securities. This compares with $14.0 million in cash and cash equivalents and $54.4 million in investments in auction rate securities at December 31, 2007. In the third quarter of 2008, we received the third and final $25.0 million milestone payment related to Shire s sales of Daytrana®. As of December 31, 2008, no amounts were outstanding under our $15.0 million revolving credit facility.

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Our investments in auction rate securities at December 31, 2008 had a fair value of $15.5 million. We liquidated $39.0 million of these investments at par value in 2008. The auction rate securities that we hold are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. During 2008, we recorded an other-than-temporary change in fair value of $0.5 million relating to our investments in auction rate securities, which was consequently recognized in our 2008 Consolidated Statement of Operations.

Total prescriptions for Vivelle-Dot® increased 6% in 2008 compared to 2007, and total prescriptions for Novogyne s HT products, taken as a whole, increased 3%. By comparison, the United States HT market declined 5% for the same period. Total prescriptions for Daytrana® decreased 11% in 2008 compared to 2007, while prescriptions for ADHD stimulant therapies as a class increased 8% over the same period. Total prescriptions for Pexeva® decreased 6% in 2008 compared to 2007, while for the same period prescriptions for the selective serotonin re-uptake inhibitor (SSRI) class increased 1%. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 31% in 2008 compared to 2007.

In July 2008, the FDA granted final approval of the New Drug Application for Stavzor® (valproic acid delayed release capsules) in the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Noven Therapeutics commercially launched Stavzor® in August 2008.

In August 2008, we entered into global license and supply agreements with Procter & Gamble Pharmaceuticals, Inc. relating to the development and commercialization of a low-dose testosterone patch for the treatment of HSDD and other indications.

In the fourth quarter of 2008, we began patient enrollment for a Phase 2 study of Mesafem, our developmental non-hormonal product for vasomotor symptoms (hot flashes), and that study is continuing, with completion expected during 2009.

Also in the fourth quarter of 2008, we terminated our agreements with Shire for the development of an amphetamine patch, and the rights to this product were returned to us. We intend to pursue the further development and commercialization of the product. As a result of the termination, we recognized $7.2 million of previously deferred payments from Shire as license revenues in the fourth quarter of 2008.

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 Noven Therapeutics, LLC in 2007

As more fully described in Note 4 Acquisition of Noven Therapeutics, LLC to the Consolidated Financial Statements, we acquired Noven Therapeutics, LLC (f/k/a JDS Pharmaceuticals, LLC) on August 14, 2007 (the Closing Date). The results of operations of Noven Therapeutics have been included in our consolidated results beginning on the Closing Date. The total purchase price for the Noven Therapeutics acquisition consisted of $125.0 million cash paid at closing, approximately $5.4 million of transaction costs consisting

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primarily of fees paid for financial advisory, legal, valuation and accounting due diligence services, approximately $0.5 million in connection with non-competition agreements entered into with two executives of Noven Therapeutics in connection with the acquisition and $1.0 million of net working capital adjustments. We funded the acquisition from the sale of short-term investments. We accounted for the acquisition of Noven Therapeutics using the purchase method of accounting. The final purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by approximately $14.4 million, which has been recorded as goodwill, all of which is deductible for tax purposes.

The final allocation of total purchase price for the acquisition to tangible and intangible assets acquired and liabilities assumed was 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):

Property, equipment and other assets	$ 525
Intangible assets:	
Acquired in-process research and development	100,150
Identifiable intangible assets	39,110
Goodwill	14,407
Net working capital, including cash of $0.6 million	(7,062)
Long-term obligation assumed	(3,711)
Contingent milestones assumed	(11,500)
Total purchase price	$ 131,919

The $100.2 million of the purchase price allocated to IPR&D 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 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 were for contingent sales milestones payable upon the achievement of specified future sales levels of Pexeva®. We became obligated to pay $6.5 million of these milestones based on 2007 and 2008 sales of Pexeva®. In the third quarter of 2008, we recognized $5.0 million in operating income as a result of the reversal of the remaining accrued liability upon our determination that the achievement of the applicable milestone was no longer probable based on projected sales of Pexeva®.

Daytrana®

Daytrana® is our transdermal methylphenidate system for the treatment of ADHD, which we have licensed globally to Shire. We and Shire have received reports from some consumers concerning the difficulty of removing the release liner from certain Daytrana® patches. In the first quarter of 2007, we, together with Shire, implemented enhancements to the Daytrana® release liner. While the enhanced release liner has reduced the level of consumer reports, some patients and caregivers continue to have difficulty in removing the release liner from some Daytrana® patches.

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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 recalls 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 those recalls. This payment was charged to operations in 2007.

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 the warning letter, which is posted at the FDA s website, the FDA cited 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 ® enhanced release liner throughout the product s shelf life. We submitted our response to the warning letter on January 30, 2008, which remains under review by the FDA.

In April 2008, a Noven stability protocol identified certain Daytrana® lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana® that did not meet the product s release liner removal specification. In August 2008, Shire initiated the voluntary recall of two additional lots of Daytrana® that did not meet the product s release liner removal specification. During 2008, we paid Shire $3.7 million related to its June and August 2008 recalls, of which approximately $3.1 million has been charged to general and administrative expenses, $0.4 million was recorded as a reduction in revenues and $0.2 million was charged to cost of products sold in 2008. For each of the recalls described above, the amount charged to general and administrative expenses represents amounts we are obligated to reimburse Shire for direct costs of the recalls, the amounts reflected as reductions of revenue represent the amounts recognized for product which is expected to be returned and the charge to cost of product sold represents the value of AMI included in such product for which we are required to reimburse Shire.

In the fourth quarter of 2008, we implemented new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Product that fails to meet this test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in the destroyed product. In 2008, Daytrana® cost of products sold exceeded our Daytrana® net revenues by $7.0 million, including $2.7 million of the 2008 Daytrana® Charges, of which $1.6 million was recorded as a reduction in revenues and $1.1 million was charged to cost of products sold. Although we have implemented new manufacturing processes that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, we expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in destroyed product, unless and until the peel force issue is resolved.

In accordance with SFAS No. 5, we have determined that certain previously-manufactured lots that would not have met the new release testing standard are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life.

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Consequently, during 2008, we established a reserve of $3.8 million related to these affected lots, which includes $1.7 million of estimated recall costs that we will be required to reimburse Shire if there are withdrawals or recalls. Of the $3.8 million reserve, approximately $1.7 million has been charged to general and administrative expenses, $1.2 million was recorded as a reduction in revenues and $0.9 million was charged to cost of products sold. We do expect that there will be an additional voluntary withdrawal/recall of some Daytrana® lots due to the peel force issue. While we believe the $3.8 million reserve is adequate for the costs of such withdrawal/recall, we cannot assure that our costs related to this issue will not exceed the amount reserved. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, we cannot assure that our testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve.

We believe we have identified the root cause of the peel force issue. We are testing manufacturing solutions designed to address the peel force issue. Implementation of the solutions being tested will require prior agreement from the FDA. Subject to FDA review and agreement, Noven s current plan calls for shipments to Shire in the third or fourth quarter of 2009. We cannot assure that the FDA will approve the solutions being tested on a timely basis or at all. Noven s warning letter remains under review by the FDA.

For a detailed discussion of the risks and uncertainties facing Daytrana®, please see the risk factor discussion beginning on page 21 of this Form 10-K.

Results of Operations

As discussed in Note 17 Segment and Customer Data to our Consolidated Financial Statements, we operate in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, our women s health joint venture with Novartis in which we own a 49% equity interest; and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products.

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Revenues:

The following table summarizes our net revenues by segment and type for our operating segments which generate revenues (dollar amounts in thousands):

	Years Ended December 31,				
	2008	% Change	2007	% Change	2006
Noven Transdermals					
Novogyne:					
Product sales	$ 21,308	-5%	$ 22,425	14%	$ 19,714
Royalties	8,411	13%	7,458	9%	6,845
Product revenues Novogyne	29,719	-1%	29,883	13%	26,559
Third Parties:					
Product sales	23,100	-11%	26,000	21%	21,422
Royalties	334	-2%	340	-1%	345
Product revenues third parties	23,434	-11%	26,340	21%	21,767
Total product revenues	53,153	-5%	56,223	16%	48,326
License and contract revenues	30,548	72%	17,725	43%	12,363
Total Transdermals	83,701	13%	73,948	22%	60,689
Noven Therapeutics					
Third Parties:					
Product sales	24,474	166%	9,213	N/M	
Net Revenues	$ 108,175	30%	$ 83,161	37%	$ 60,689

N/M Not Meaningful

Net Revenues

As described in more detail below, the 30% increase in net revenues for 2008 as compared to 2007 was primarily attributable to the addition of $24.5 million in net revenues reflecting a full year of sales of Noven Therapeutics products, as compared to 4.5 months of sales in 2007. We also realized a $12.8 million, or 72%, increase in license and contract revenues compared to 2007, which was primarily attributable to an increase in amortization of Daytrana® milestones and $7.2 million of revenue recognized upon termination of an amphetamine development agreement in the fourth quarter of 2008. These increases were partially offset by a $3.1 million decrease in product revenues from our Noven Transdermals segment comprised primarily of a $2.6 million decrease in sales of Daytrana® in 2008.

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 Noven Therapeutics.

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Product Revenues Novogyne

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

The $0.2 million decrease in product revenues from Novogyne for 2008 compared to 2007 primarily resulted from a $1.5 million decline of Vivelle-Dot® product revenues, partially offset by an increase of $1.0 million in royalties due to increased sales by Novogyne to its customers for 2008, as well as a $0.5 million increase in unit sales of CombiPatch® due to the timing of orders from Novogyne. The decline in Vivelle-Dot® product revenues is attributable to the timing of orders as prescriptions have increased period to period. The previously disclosed backlog of orders due to the first quarter 2008 production issues was completely filled as of December 31, 2008.

The $3.3 million increase in product revenues from Novogyne for 2007 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.

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 consist 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 Estradot® in Canada; (ii) sales of Daytrana® to Shire for commercial resale in the United States; (iii) beginning on August 14, 2007, Noven s commercial sales of Pexeva® and Lithobid® to trade customers, including wholesalers, distributors and chain pharmacies; and (iv) beginning in August 2008, sales of Stavzor® to trade customers, including wholesalers, distributors and chain pharmacies.

As discussed above, the increase in net revenues for 2008 compared to 2007 for our Noven Therapeutics segment was primarily attributable to $24.5 in net revenues in 2008 reflecting a full year of sales compared to $9.2 million in net revenues in 2007, reflecting only 4.5 months of sales following the Noven Therapeutics acquisition.

The $2.9 million decrease in product revenues third parties in our Noven Transdermals segment for 2008 compared to 2007 primarily consisted of a $2.6 million decline in sales of Daytrana® and a $0.6 million decline in third-party revenues from our HT products due to a decrease in pricing. The decrease in Daytrana® product revenues was largely attributable to delays in the release of product in 2008, an aggregate $1.6 million reduction in revenues related to expected Daytrana® product returns due to peel force issues on sold product, the timing of orders and, to a lesser extent, decreased demand. In addition, Noven realized a lower benefit from price increases for our third party HT product through periodic price reconciliation payments received from Novartis as further described below. We recognized $2.4 million and $3.1 million of such payments in 2008 and 2007, respectively.

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The $4.6 million increase in product revenues third parties in our Noven Transdermals segment for 2007 compared to 2006 primarily related to $4.7 million increase in volume sales of Daytrana® 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 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® was due to the timing of orders.

We sell Stavzor® to pharmaceutical wholesalers and chain drug stores. These companies have the right to return Stavzor® for up to one year after product expiration. As a result of the commercial launch of Stavzor® in the third quarter of 2008, we do not have sufficient sales history to reasonably estimate product returns. Under SFAS No. 48, we cannot recognize revenue on product shipments until we can reasonably estimate returns relating to these shipments. In accordance with SFAS No. 48, we defer recognition of revenue on product shipments of Stavzor® to our customers until such time as Stavzor® units are dispensed through patient prescriptions, since our customers are no longer permitted to return the product once it has been dispensed. We estimate the volume of prescription units dispensed at pharmacies based on data provided by external, independent sources. These sources poll pharmacies, hospitals, mail order and other retail outlets for Stavzor® prescriptions and project this sample on a national level. We will recognize revenue based on prescription units dispensed until we have sufficient sales history to reasonably estimate product returns. We recognized $0.4 million of net revenues for Stavzor® in 2008, and $1.5 million remained in deferred product revenue on our Consolidated Balance Sheet as of December 31, 2008.

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 and contract revenues increased $12.8 million for 2008 compared to 2007, primarily due to (i) a $4.8 million increase in amortization of milestone payments received from Shire related to the license of Daytrana®; (ii) $7.2 million related to the termination of the amphetamine patch project with Shire as described below; and (iii) an $0.8 million increase in contract revenues due to additional work performed on developmental products. The $4.8 million increase in amortization of milestone payments reflects a full year of amortization of the second $25.0 million Daytrana® sales milestone payment received during the third quarter of 2007 and additional amortization of the third $25.0 million Daytrana® sales milestone payment received in the third quarter of 2008.

In connection with our collaboration with Shire for the development of an amphetamine patch, Shire paid us an aggregate $7.2 million, including payments for development and for the exclusive developmental rights to the product. These $7.2 million of payments received were included in deferred license and contract revenues on our Consolidated Balance Sheet as of December 31, 2007.

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On November 5, 2008, we entered into a letter agreement (the Termination Agreement) with Shire terminating our agreements with Shire relating to an amphetamine patch. The Termination Agreement terminates the amphetamine collaborative agreements with Shire dated as of (i) June 15, 2004, (ii) May 4, 2007, and (iii) June 4, 2007. Under the Termination Agreement, rights to the developmental amphetamine patch were returned to us. We currently intend to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if we elect to commercialize a product that incorporates intellectual property arising from the development project with Shire. As a result of the termination of this project with Shire, we recognized the $7.2 million as license and contract revenues in the fourth quarter of 2008.

License revenues increased $6.9 million for 2007 compared to 2006, which is primarily 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 compared to 2006, primarily reflecting a decline in contract work performed.

Gross to Net Revenues

We record revenues net of sales allowances for rebates, chargebacks, cash and other discounts, as well as sales returns allowances. Sales returns allowances represent management s best estimate of the amount of product shipped to customers that will be returned in the future. Such estimates consider a variety of factors which can differ depending on the nature of the product, customer sales terms and historical return rates. Our Transdermal products are generally sold to partners and are typically not subject to return based on expiration dating. However, the products are subject to return based on manufacturing and quality specifications and, therefore, may be subject to product recall. We establish return allowances on product sold through our Transdermals segment when it is probable that such product will be recalled or withdrawn. Sales returns allowances in our Noven Therapeutics segment represent allowances for estimated product returns based on expiration dating and are estimated based on historical return rates, current sales levels and other factors on a product-by-product basis. During each of 2008 and 2007, sales returns allowances for Noven Transdermals increased $0.7 million primarily due to Shire s voluntary recalls of certain Daytrana® product. For the Noven Therapeutics segment, during 2008, allowances for Medicaid, Medicare & State program rebates and credits including redemption offers decreased 4% as a percentage of revenue due to the non-renewal of certain unprofitable state Medicaid contracts. Sales returns allowances for the Noven Therapeutics segment increased 4% due to an increase in actual returns of Pexeva® and Lithobid® product. All other sales allowances for the Noven Therapeutics segment were consistent in 2008 and 2007, as a percentage of revenue.

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The following table sets forth the reconciliation of our gross revenues to net revenues (dollar amounts in thousands):

	Years Ended December 31,					
	2008	% of gross revenues	2007	% of gross revenues	2006	% of gross revenues
Noven Transdermals:						
Gross revenues	$ 85,317	100%	$ 74,903	100%	$ 60,982	100%
Sales returns allowances	(1,616)	-2%	(955)	-1%	(293)	0%
Net revenues	$ 83,701	98%	$ 73,948	99%	$ 60,689	100%
Noven Therapeutics:						
Gross revenues	$ 39,196	100%	$ 14,579	100%		
Cash discounts	(835)	-2%	(285)	-2%		
Medicaid, Medicare & State program rebates and credits including redemption offers	(7,285)	-19%	(3,289)	-23%		
Chargebacks	(1,315)	-3%	(351)	-2%		
Wholesaler fees	(1,877)	-5%	(775)	-5%		
Sales returns allowances	(3,410)	-9%	(666)	-5%		
Sales and returns allowances	(14,722)	-38%	(5,366)	-37%		
Net revenues	$ 24,474	62%	$ 9,213	63%		

Gross Margin

This section discusses gross margins relating to our product revenues: (i) across all of our products (Overall Gross Margin); (ii) on our transdermal product revenues from Novogyne (Gross Margin Novogyne), which for accounting purposes is considered a related party; (iii) on our transdermal product revenues from third parties (Gross Margin Third Parties); and (iv) on our Noven 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. Noven Therapeutics product revenues include sales of Stavzor®, Pexeva® and Lithobid® to trade customers.

For our Noven Transdermals segment, the allocation of manufacturing expenses impacts our determination of inventory costs and, consequently, gross margins for each of our products. Manufacturing expenses, which totaled $31.0 million, $25.9 million and $26.2 million in 2008, 2007 and 2006, respectively, include compensation 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 manufacturing expenses among manufactured 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.

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

	Years Ended December 31,					
	2008		2007		2006	
Noven Transdermals						
Novogyne:						
Product revenues	$ 29,719		$ 29,883		$ 26,559	
Cost of products sold	15,134		13,683		14,102	
Gross profit	14,585	49%	16,200	54%	12,457	47%
Third parties:						
Product revenues	23,434		26,340		21,767	
Cost of products sold	28,689		24,188		22,406	
Gross profit (loss)	(5,255)	-22%	2,152	8%	(639)	-3%
Total Noven Transdermals						
Product revenues	53,153		56,223		48,326	
Cost of products sold	43,823		37,871		36,508	
Gross profit	9,330	18%	18,352	33%	11,818	24%
Noven Therapeutics						
Product revenues	24,474		9,213			
Cost of products sold	8,038		3,146			
Gross profit	16,436	67%	6,067	66%		
Total Company						
Product revenues	77,627		65,436		48,326	
Cost of products sold	51,861		41,017		36,508	
Gross profit	$ 25,766	33%	$ 24,419	37%	$ 11,818	24%

In general, Noven Therapeutics products have higher gross margins than our transdermal products because we sell Noven Therapeutics 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 lower gross margins 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 declined in 2008 compared to 2007. Overall Gross Margin in 2008 was negatively affected by: (i) inventory write-offs of $2.8 million, primarily related to an equipment failure

in transdermal manufacturing (comprised of $1.8 million of write-offs of products manufactured for Novogyne and $1.0 million of third party HT product write-offs), as well as additional manufacturing costs incurred in 2008 to address this issue; (ii) cost of products sold in 2008, which included $1.1 million of the 2008 Daytrana® Charges; (iii) inventory write-offs of approximately $1.5 million related to Daytrana® product; (iv) the addition of approximately

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$5.1 million in manufacturing costs in our Noven Transdermals segment over 2007, primarily in the quality assurance area, of which approximately $1.4 million related to costs associated with the Daytrana® peel force issue; and (v) significantly lower product revenues in our Noven Transdermals segment, primarily related to the timing of shipments and delays in the release of Daytrana® product in 2008. Overall Gross Margin in 2008 benefited from the addition of our Stavzor®, Pexeva® and Lithobid® products, which collectively had net sales of $24.5 million and related cost of products sold of $8.0 million, resulting in a gross margin of 67% for those products and a decrease in product inventory at Novogyne which resulted in approximately $0.4 million of recognized deferred profit on product sold to Novogyne.

As noted in the tables above, Overall Gross Margin improved significantly in 2007 compared to 2006. Overall Gross Margin in 2007 benefited from: (i) 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; (ii) 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 (iii) 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.

We sell Daytrana® finished product to Shire at a fixed cost, and consequently, our profit on product sales of Daytrana® depends on our ability to manufacture the product efficiently and to fully utilize our facilities. For 2008, Daytrana® net product revenues were $10.8 million and cost of products sold related to Daytrana® was $17.8 million, resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $13.4 million and cost of products sold related to Daytrana® of $14.8 million for 2007. Daytrana® gross margin was negatively affected in 2008 by the 2008 Daytrana® Charges as well as increased manufacturing and quality assurance related expenditures, including, as discussed above, approximately $1.4 million related to costs associated with the Daytrana® peel force issue. Although we have implemented new manufacturing processes that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, we expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in destroyed product, unless and until the peel force issue is resolved.

We expect to continue to incur increased quality assurance costs related to our continued efforts to improve our quality assurance systems and to address the issues raised by the FDA and a significant portion of these continuing costs will be allocated to Daytrana®, which we expect to negatively affect the gross margin on sales of this product in 2009 and beyond.

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

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Operating Expenses:

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

	Years Ended December 31,				
	2008	% Change	2007	% Change	2006
Research and development	$15,527	11%	$ 13,978	22%	$11,454
Acquired in-process research and development		N/M	100,150	N/M	
Selling and marketing	23,299	154%	9,160	847%	967
General and administrative	36,796	21%	30,411	47%	20,734

N/M Not Meaningful

Research and Development

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

The $1.5 million increase in research and development expenses for 2008 compared to 2007 was attributable to a $2.0 million increase in clinical research and development, primarily for Mesafem , partially offset by a $0.5 million decrease in clinical research costs for other developmental products.

The $2.5 million increase in research and development expenses for 2007 compared to 2006 was primarily due to a $1.9 million increase in clinical research costs on transdermal developmental products and $1.5 million in expenses as a result of the acquisition of Noven Therapeutics. 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.

Acquired In-Process Research and Development

Immediately following the closing of the Noven Therapeutics acquisition, we expensed $100.2 million in 2007 representing the portion of the purchase price allocated to in-process research and development in our acquisition of Noven Therapeutics. 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.

Selling and Marketing

The $14.1 million increase in selling and marketing costs for 2008 compared to 2007 were attributable to the addition of Noven Therapeutics in August 2007, which added $14.5 million of selling and marketing costs in 2008, including $4.8 million related to Stavzor®, which was launched in August 2008.

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The $8.2 million increase in selling and marketing costs for 2007 compared to 2006 were primarily attributable to the addition of Noven Therapeutics in August 2007, related to the sales and marketing of Pexeva® and Lithobid®.

General and Administrative

General and administrative expenses increased $6.4 million, or 21%, for 2008 compared to 2007, reflecting $4.8 million of the 2008 Daytrana® Charges (compared to $2.2 million in 2007), a $1.8 million charge related to a patent infringement case, a $1.5 million increase in salary and related benefits primarily as a result of filling key executive positions, a $1.4 million increase in professional fees, primarily attributable audit and accounting fees and executive recruiting, a $0.6 million loss on the disposal of assets, and a $1.8 million increase across other general and administrative expense categories. These increases were partially offset by the absence of a $3.3 million charge recorded in 2007 related to certain executive separations.

General and administrative expenses increased $9.7 million, or 47%, for 2007 compared to 2006. The increase was attributable to a $3.9 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 Shire s 2007 voluntary recalls of Daytrana®, a $2.1 million increase as a result of the addition of Noven Therapeutics and a $1.6 million increase in professional fees.

Reversal of Contingent Milestone Liability

In 2008, we recognized $5.0 million in operating income as a result of the reversal of an accrued liability for the final contingent milestone payment to Synthon upon a determination that the achievement of the final sales milestone for annual net sales of Pexeva® was no longer probable.

Other Income and Expenses

Interest and Other Income

Interest and other income decreased $3.4 million, or 63%, in 2008 compared to 2007. This decrease was primarily attributable to a decrease in cash available for investment as a result of the payment of $130.4 million in connection with the Noven Therapeutics acquisition in August 2007, as well as additional sales of auction rate securities at par during 2008 and lower interest rates on our remaining investments.

Interest and other income increased $1.2 million, or 28%, in 2007 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 offset by the $130.4 million in cash consideration related to the Noven Therapeutics acquisition, which decreased our cash available for investment in the third and fourth quarter of 2007.

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Income Taxes

Our effective tax rate was approximately 35% for 2008 and 2007 and 33% for 2006. 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 Noven Therapeutics resulted in a significant increase in our deferred income tax assets, primarily due to the $100.2 million of acquired in-process research and development which was expensed immediately under GAAP, but is being deducted over 15 years for tax purposes. As of December 31, 2008 we had a net deferred tax asset of $72.2 million compared to $65.7 million at December 31, 2007. 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. Noven Therapeutics has historically reported taxable losses in these states and we expect that Noven Therapeutics will continue to incur state taxable losses in the next few years. These circumstances create negative evidence indicating the need for a valuation allowance at December 31, 2008. Our valuation allowance for state deferred tax assets was $3.5 million and $3.2 million as of December 31, 2008 and 2007, respectively, due to uncertainty about our ability to realize these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future profitability of Noven Therapeutics that these state deferred tax assets will more likely than not 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 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-exempt interest income as a percentage of our total loss due to the sale of investments to fund the Noven Therapeutics acquisition.

Equity in Earnings of Novogyne

We share in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of $6.1 million to Novartis. Our share of Novogyne s earnings (a non-cash item) increases as Novogyne s earnings increase, subject to a cap of 49%. Novogyne earned sufficient income in each of 2008, 2007 and 2006 to meet Novartis annual preferred return for those periods and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne s earnings as Equity in earnings of Novogyne in our Consolidated Statements of Operations.

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Novogyne records revenues net of sales allowances for rebates, chargebacks, cash and other discounts and sales returns allowances. The financial results of Novogyne are summarized as follows (dollar amounts in thousands):

	Years Ended December 31,				
	2008	% Change	2007	% Change	2006
Gross revenues	$ 197,994	16%	$ 171,347	11%	$ 154,901
Sales allowances	23,731	8%	21,912	27%	17,226
Sales returns allowances	4,645	221%	1,447	-75%	5,732
Sales and returns allowances	28,376	21%	23,359	2%	22,958
Net revenues	169,618	15%	147,988	12%	131,943
Cost of sales	33,795	8%	31,203	3%	30,149
Gross profit	135,823	16%	116,785	15%	101,794
Gross margin percentage	80%		79%		77%
Selling, general and administrative expenses	37,471	-2%	38,084	2%	37,319
Income from operations	98,352	25%	78,701	22%	64,475
Interest income and other	1,129	-1%	1,145	36%	842
Net income	$ 99,481	25%	$ 79,846	22%	$ 65,317
Noven s equity in earnings of Novogyne	$ 45,642	27%	$ 35,850	25%	$ 28,632

Novogyne Net 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 quarterly results.

Novogyne s gross revenues increased $26.6 million for 2008 compared to 2007. By product, Vivelle-Dot® and CombiPatch® increased $30.9 million and $1.0 million, respectively, while Vivelle® (a discontinued product) decreased $5.4 million. The $30.9 million Vivelle-Dot® increase consisted of a $19.0 million increase related to pricing and an $11.9 million increase in unit sales, which is consistent with increases in prescription trends. The $1.0 million CombiPatch® increase was attributable to a $1.5 million increase related to pricing, partially offset by a $0.5 million decline in unit sales which resulted from a continued decline in the market for combination therapies, and the impact of a competitive product.

Novogyne s gross revenues increased $16.4 million for 2007 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

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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 an increase in the pricing of the product.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. For 2008, 2007 and 2006, these sales allowances were 12%, 13% and 11%, respectively, of gross revenues.

The following table describes Novogyne s sales and returns allowances (dollar amounts in thousands):

	Years Ended December 31,					
	2008	% of gross revenues	2007	% of gross revenues	2006	% of gross revenues
Gross revenues	$ 197,994	100%	$ 171,347	100%	$ 154,901	100%
Managed health care rebates	14,578	7%	13,226	8%	10,117	7%
Cash discounts	3,920	2%	3,387	2%	3,042	2%
Medicaid, Medicare & State program rebates and credits including prescription drug saving cards	1,340	1%	1,637	1%	981	1%
Chargebacks, including hospital chargebacks	1,423	1%	1,298	1%	1,032	1%
Other discounts	2,470	1%	2,364	1%	2,054	1%
Sales allowances	23,731	12%	21,912	13%	17,226	11%
Sales returns allowances	4,645	2%	1,447	1%	5,732	4%
Sales and returns allowances	28,376	14%	23,359	14%	22,958	15%
Net revenues	$ 169,618	86%	$ 147,988	86%	$ 131,943	85%

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Sales returns allowances consist of allowances for returns of expiring product. The activity in the sales returns allowances was as follows (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Sales returns allowances included in net revenues	$ 4,645	$ 1,447	$ 5,732
Actual returns primarily for expiring product	(3,466)	(3,349)	(3,962)
Change in allowances for returns primarily for expiring product	$ 1,179	$ (1,902)	$ 1,770

The increase in sales returns allowances for 2008 compared to 2007 is primarily attributable to an increase in sales of Vivelle-Dot® as well as a revision to the return rate for Vivelle-Dot® in the current period due to an increase in the rate of actual returns for the product. In addition, 2007 benefited from a reduction in allowances for expiring product due to lower than expected returns as a result of a decline in actual returns of CombiPatch® at the time.

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

Novogyne Gross Margin

The increase in gross margin percentage for 2008 as compared to 2007 was primarily related to higher sales of Vivelle-Dot®, which has a higher gross margin than the other products sold by Novogyne, as well as price increases for all products, partially offset by higher sales returns allowances due to the increase in such allowances for Vivelle-Dot®.

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 Selling, General and Administrative

Novogyne s selling, general and administrative expenses decreased $0.6 million for 2008 compared to 2007 primarily due to a $0.8 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne and an aggregate $0.2 million decrease in marketing, advertising and promotional expenses attributable to product marketing efficiency efforts. These decreases were partially offset by a $0.4 million increase in HT litigation expenses.

Novogyne s selling, general and administrative expenses increased $0.8 million for 2007 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.

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Liquidity and Capital Resources

As of December 31, 2008 and December 31, 2007, Noven had the following (amounts in thousands):

	December 31,	
	2008	2007
Cash and cash equivalents	$62,875	$13,973
Short-term investments	3,650	21,565
Working capital	50,644	24,024

In addition to our cash and working capital, as of December 31, 2008, we owned investments in auction rate securities with a fair value of $15.5 million, of which $3.7 million has been called by the issuer and is included in current assets. Due to the current illiquid market conditions and failed auctions, we have classified the remaining $11.8 million of these investments as non-current assets; however, these investments have been a source of liquidity during 2008, including proceeds of $39.0 million from sales and redemptions of these auction rate securities at par during 2008. On a combined basis, our cash and cash equivalents and investments in auction rate securities were as follows (amounts in thousands):

	December 31,	
	2008	2007
Cash and cash equivalents	$ 62,875	$ 13,973
Investments in auction rate securities:		
Current	3,650	21,565
Non-current	11,810	32,835
Total cash and cash equivalents and investments	$ 78,335	$ 68,373

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

	Years Ended December 31,		
	2008	2007	2006
Cash flows:			
Operating activities	$ 19,597	$ 54,369	$ 60,027
Investing activities	32,273	(43,499)	(133,511)
Financing activities	(2,968)	(6,041)	15,664
Net cash flows	$ 48,902	$ 4,829	$ (57,820)

Operating Activities

Net cash provided by operating activities for 2008 primarily resulted from the receipt of $42.0 million in distributions from Novogyne and a $25.0 million milestone payment from Shire. Significant operating cash outflows during 2008 included income tax payments of $20.8 million, $5.4 million of employee severance, bonus and retention payments, payments to Shire of $3.7 million and $3.3 million related

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to its 2008 and 2007 voluntary recalls of certain Daytrana® product, respectively, and $3.5 million in payments related to insurance premiums. In addition, changes in working capital, including a $6.8 million increase in inventories and a $1.8 million decrease in accrued compensation and related liabilities, also partially offset the net cash provided by operating activities.

Net cash provided by operating activities for 2007 primarily resulted from the 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 collaborative 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 in insurance payments and an increase of $3.1 million in compensation and related liabilities.

Net cash provided by operating activities in 2006 primarily resulted from the 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.

Investing Activities

Noven has invested a portion of its cash in investments, which primarily consist of investment grade, 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 provided by investing activities for 2008 was primarily attributable to $39.0 million in sales of investments at par, partially offset by $3.8 million in equipment purchases to support operations and a $1.5 million milestone payment to Banner upon approval of Stavzor® in the third quarter of 2008.

Net cash used in investing activities for 2007 was primarily attributable to $130.4 million in acquisition costs related to the acquisition of Noven Therapeutics, 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 the sale of short-term investments primarily used to fund the Noven Therapeutics 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.

Financing Activities

Net cash used in financing activities for 2008 was primarily attributable to a $3.3 million sales milestone payment to Synthon, an obligation assumed as part of the Noven Therapeutics acquisition.

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Net cash used in financing activities for 2007 was primarily attributable to the open-market purchase of $5.1 million 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 Noven Therapeutics. These payments were offset by $2.5 million received as the exercise price paid by option holders in connection with 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 was attributable to $13.2 million received as the exercise price paid by the option holders in connection with the exercise 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 distributions from Novogyne. Additional sources of short-term liquidity include cash generated from product sales, license fees and royalties under development and license agreements.

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 increases 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 require us to rely on our existing cash balances, investments, equity or debt offerings or on borrowings to support our operations and business.

During 2008, our cash and cash equivalents and investments in auction rate securities increased from $68.4 million to $78.3 million. The increase primarily resulted from the receipt of the third and final $25.0 million sales milestone payment from Shire and $42.0 million of distributions from Novogyne. The cash increases were partially offset by certain cash outlays in 2008, including (i) $20.8 million of income tax payments in 2008; (ii) $3.8 million for equipment purchases; (iii) $3.7 million of payments to Shire for Shire s voluntary withdrawals of Daytrana® product in 2008; (iv) $3.5 million for insurance premiums; (v) a $1.5 million milestone payment in connection with market approval for Stavzor®; and (vi) cash used to fund increases in inventory and other working capital items. In addition, we also paid certain obligations previously charged to operations in 2007 and/or accrued as of December 31, 2007, including (i) $5.4 million of employee severance, bonus and retention payments; (ii) $3.3 million of costs associated with Shire s 2007 voluntary withdrawals of Daytrana® product; and (iii) a $3.3 million milestone payment related to Noven Therapeutics products. We believe that our existing cash balances and expected collections of receivables, together with the available capacity under our credit facility (described below), will be sufficient to meet our operating needs and short-term capital requirements.

We received the first $25.0 million sales milestone payment from Shire relating to its sales of Daytrana® in the first quarter of 2007, the second $25.0 million Daytrana® sales milestone payment in the third quarter of 2007 and the third $25.0 million Daytrana® sales milestone payment in the third quarter of 2008. We paid an aggregate $20.8 million and $23.7 million in taxes during 2008 and 2007, respectively, of which approximately $8.8 million and $18.0 million relates to Daytrana® milestones received to date. We expect to pay income taxes related to the final Daytrana® milestone payment of approximately $8.5 million during 2009.

As discussed elsewhere herein, we paid Shire $3.7 million related to Shire s voluntary recalls of Daytrana® product in 2008. In addition, we reserved $3.8 million in 2008 for certain previously-manufactured Daytrana® lots that would not meet the new release testing standard and

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are probable of being voluntarily withdrawn or recalled from the market prior to expiration of their shelf life, and which therefore would require additional reimbursements to Shire.

In April 2008, we made a $3.3 million milestone payment to Synthon based on achieving specified net sales of Pexeva® during 2007. We expect to pay an additional $3.3 million milestone to Synthon in 2009 based on 2008 net sales of Pexeva®.

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 . During 2008, we recorded $0.5 million of other-than-temporary impairments on our investments in auction rate securities which are classified as available-for-sale under SFAS No. 115. As of December 31, 2008, the total par value and fair value of our investments in auction rate securities was $16.0 million and $15.5 million, respectively. We liquidated $39.0 million of our investments in auction rate securities at par value during 2008. An additional $3.7 million has been called by the issuer and is expected to be redeemed in March 2009. Due to continuing auction failures beginning in February 2008, we utilized valuation models to determine the fair values of our investments in auction rate securities. The fair values of our investments were calculated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

Changes to investments measured at fair value on a recurring basis using unobservable inputs (Level 3) during 2008 were as follows (amounts in thousands):

Balance at December 31, 2007	$ 54,400
Purchases of investments	550
Sales of investments at par	(38,975)
Unrealized losses, other-than-temporary	(515)
Balance at December 31, 2008	$ 15,460

As a result of failed auctions, our auction rate securities pay interest at rates as defined by the governing documents or indenture. Due to uncertainty regarding the timing of our future investment liquidations, we have classified our auction rate securities as non-current assets as of December 31, 2008, except for the called security, which is included in current assets. As illiquid conditions persist in the auction market for these securities, it may become increasingly more likely that we will need to recognize additional other-than-temporary impairment charges in future periods. Such non-cash impairment charges could materially and adversely affect our consolidated financial condition and results of operations.

We paid approximately $125.0 million in cash to acquire Noven Therapeutics in August 2007 and incurred approximately $5.4 million in transaction-related costs. We funded the purchase price and related transaction expenses from our sale of short-term investments. In addition, we assumed approximately $16.1 million of accrued expenses and other current liabilities and assumed certain contractual arrangements under which we may be required to pay to third parties up to $8.3 million in product development and sales milestones as of December 31, 2008. See Note 19 Commitments and Contingencies Noven Therapeutics Commitments in the Notes to our Consolidated Financial Statements for further information.

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During 2008, proceeds from stock option exercises were not significant. We expect the amount of proceeds from stock option exercises to fluctuate from period to period depending on the price of our 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 us with cash upon their exercise. Accordingly, we expect that funds received from option exercises will become less of a source of funds over time.

In July 2008, we entered into an agreement for a $15.0 million credit facility. In connection with the credit facility and in lieu of granting a security interest in our assets, we agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of our financial assets. The facility expires in July 2009. As of the date of this report, no borrowings were outstanding under this facility and we have no long-term debt. To the extent the sources of liquidity described above are insufficient to fund our operations, we would expect to seek to obtain funds through debt and/or equity financing. 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, 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 subject us 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. We expect that we will be required to seek debt and/or equity financing to complete such an acquisition. Current conditions in the credit markets and equity markets could make it particularly difficult to raise funds on attractive terms, if at all. 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 $3.8 million for 2008. We expect to fund our foreseeable capital expenditures from our operating cash flows, existing cash, short-term investments and debt.

If our transdermal products under development are successful, we may need to fund plant and equipment purchases to expand production capacity. For our long-term operating needs, we intend to utilize funds derived from the sources described above. 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 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.

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For the years ended December 31, 2008, 2007 and 2006, our equity in earnings of Novogyne and the recognition of deferred license and contract revenues (both of which are non-cash items) contributed significantly to our income before income taxes. Accordingly, our net income 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, 2008 (amounts in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations[1]	$ 6,560	$ 1,407	$ 2,294	$ 1,968	$ 891
Capital Lease Obligation[2]	188	155	16	16	1
Deferred Compensation Obligation	515	139	195	67	114
Long-Term Obligations[3]	3,250	3,250			
Purchase Obligations[4]	26,293	26,289	4		
Unrecognized Tax Benefits	1,343	302	236	565	240
Total	$ 38,149	$ 31,542	$ 2,745	$ 2,616	$ 1,246

[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 $2.1 million, $1.5 million and $1.2 million for the years ended December 31, 2008, 2007 and 2006, respectively.

[2] Noven did not enter into capital lease obligations in

2008. During 2007 and 2006, Noven entered into capital lease obligations for new equipment totaling $0.1 million and $0.4 million, respectively, of which $0.2 million (including interest) remains outstanding as of December 31, 2008.

[3] Represents $3.3 million sales milestone payable in 2009 based on 2008 sales of Pexeva®.

[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.

Outlook

A summary of our current financial guidance is provided below. 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 based upon matters beyond our control. In particular, for purposes of this guidance we have assumed that, during 2009, there will not be any material:

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

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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, unexpected 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, health care reimbursement policies 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 information contained in this Form 10-K and in other reports filed from time to time with the Securities and Exchange Commission.

Net revenues, gross margin, expenses, net income 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 2009 to be in the range of $110 million to $115 million, including license and contract revenues of approximately $26 million.

Gross Margin. We expect our overall gross margin, as a percentage of total net product revenues, to be in the range of 38% to 42% for full year 2009, with a higher gross margin expected in the second half of 2009 than in the first half, reflecting our belief that our gross margin on Daytrana® should improve following commercial production of Daytrana® product incorporating a solution to the peel force issue. If, however, we are unsuccessful in addressing the peel force issue on our expected timeline, our overall gross margin for 2009 would be lower than our forecast range.

Research and Development Expense. We expect our consolidated research and development expense for full year 2009 to be in the low-to-mid $20 million range, reflecting (among other clinical projects) the cost of our ongoing Phase 2 study for Mesafem . 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 2009 to be in the mid $50 million range.

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Noven Therapeutics. We expect to improve the pre-tax contribution from our Noven Therapeutics segment by approximately $5.0 million in full year 2009 compared to 2008 levels.

Equity in Earnings of Novogyne. We expect our equity in earnings of Novogyne to be in the low-to-mid $50 million range for full year 2009.

Earnings Per Share. For full year 2009, we expect to report diluted earnings per share in the range of $0.85 to $0.95 per share.

Cash. We expect to use approximately $5 million to $10 million of cash in 2009 as we continue to invest in Mesafem™ and other programs intended to drive longer-term growth.

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 consist of the recognition of non-refundable 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 SEC s Staff Accounting Bulletin Topic 13, Revenue Recognition, and Emerging Issues Task Force (EITF) Issue 00-21, Revenue Arrangements with Multiple Deliverables (EITF Issue 00-21), 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.

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In general, revenues from non-refundable, 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. Historically, we have applied the guidance of EITF Issue 00-21, and have typically determined that the multiple 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 non-refundable 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 relating 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 non-refundable 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.

Shire Collaboration Daytrana®

In 2003, we entered into a collaboration wherein we entered into a license agreement with Shire to market and sell Daytrana® and entered into a manufacturing and supply agreement under which we agreed to supply product to Shire. We determined that the arrangement included 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 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 separate 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

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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.

In our collaboration with Shire, we receive 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.

Contract Revenues

Contract revenues consist of the recognition 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:

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

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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, 2008 (amounts in thousands):

	January 1, 2008	Payments	Income Statement Charge (Reversal) Adjustments of prior years	Current Year	December 31, 2008
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 896	$ (1,503)	$ (251)	$ 1,591	$ 733
Managed health care rebates	6,149	(13,088)	(11)	14,589	7,639
Chargebacks, including hospital chargebacks	111	(1,426)		1,423	108
Cash discounts, direct customer discounts & other discounts	1,054	(6,579)		6,390	865
Sales returns allowances	6,036	(3,466)	663	3,982	7,215
Total	$ 14,246	$ (26,062)	$ 401	$ 27,975	$ 16,560

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

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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 12 months after the product has expired. An allowance for estimated sales returns is recorded based on: (i) the historical experience of actual product returns; and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate. Novogyne also considers trends and expectations for future demand and trade inventory levels. These policies cause a significant lag time between when a product is sold and the latest date on which a return could occur. Novogyne believes this is a reasonable basis on which to estimate returns exposure and incorporates the key 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

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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. 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 cannot 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 of the product to the customer. 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 year ended December 31, 2008 (amounts in thousands):

	January 1, 2008	Payments	Income Statement Charges: Current Year	Other Adjustments	December 31, 2008
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 4,065	$ (8,624)	$ 7,285	$	$ 2,726
Chargebacks, including hospital chargebacks	139	(1,294)	1,315		160
Cash discounts	59	(817)	835		77
Other discounts	770	(2,053)	1,877		594
Sales returns allowances	1,875	(2,015)	3,410	(200) [1]	3,070
Total	$ 6,908	$ (14,803)	$ 14,722	$ (200)	$ 6,627

[1] Represents credits expected to be issued against customer receivable balances related to product returns.

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, except for Stavzor®, for which we do not yet have sufficient sales history to reasonably estimate returns.

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 12 months of remaining shelf-life and generally returns due to expiration will be accepted within 12 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.

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

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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.

During 2008, we finalized the purchase price allocation for our Noven Therapeutics acquisition, resulting in a $0.3 million net reduction in goodwill.

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 Noven Therapeutics, in addition to the value of acquired tangible assets and assumed liabilities, we ultimately recorded on our balance sheet $39.1 million of identifiable intangible assets, $14.4 million of goodwill, and $11.5 million of liabilities for contingent payments we expected 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. In accordance with SFAS No. 141, Business Combinations (SFAS No. 141), which applied to acquisitions prior to January 1, 2009, the value allocated to IPR&D 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.

Our goodwill is assigned to our Noven Therapeutics reporting segment. Goodwill is tested for impairment annually in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying value of 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

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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 asset exceeds its fair value.

As of December 31, 2008, 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 could differ from current expectations. 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 was 35% in 2008 and 2007and 33% in 2006. If our effective tax rate differed from our estimate, our results would vary.

Accounting principles generally accepted in the United States require that we record a valuation allowance against our net deferred tax asset if we cannot conclude that we will more likely than not be able to generate sufficient future taxable income to utilize our net deferred tax asset. At December 31, 2008 and December 31, 2007, net deferred tax assets were $72.2 million and $65.7 million, respectively.

Realization of these deferred tax assets depends upon the generation of sufficient future taxable income. 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. 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. Noven Therapeutics has historically reported taxable losses in these states and we expect that Noven Therapeutics will continue to incur state taxable losses in the next few years. These expected taxable losses create negative evidence indicating the need for a valuation allowance at December 31, 2008 and December 31, 2007. Our valuation allowance for state deferred tax assets was $3.5 million and $3.2 million as of December 31, 2008 and December 31, 2007, respectively, due to uncertainty about our ability to realize these state deferred tax assets based on our projection of future state taxable income relating to Noven Therapeutics. If we determine, based on future Noven Therapeutics profitability that these state deferred tax assets will more likely than not 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.

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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 $4.8 million, $5.4 million and $3.3 million in 2008, 2007 and 2006, respectively.

We 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.

The expected term of stock options/SSARs is defined as the expected time that options will remain outstanding assuming they are not forfeited prior to the vest date. We estimate the expected term using a statistical predictive model that incorporates Noven s historical exercise activity in conjunction with Noven s post-vest termination information. 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 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 $30.0 million in 2008, include salaries and benefits, supplies and tools, equipment

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costs, depreciation and insurance costs and represent a substantial portion of our inventory 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 $13.9 million and $12.1 million as of December 31, 2008 and 2007, 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, 2008, Novogyne had a long-term intangible asset of $13.9 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, the CombiPatch® marketing rights are assessed for impairments whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future net cash flows of the product. This analysis requires Novogyne to make a number of significant assumptions and judgments involving prescription trends, sales price, unit cost and product life cycle among many other factors. In the event the carrying value of the asset exceeds the undiscounted future net cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would reduce net income in the period that the impairment occurs. Events which could give rise to impairments include a number of inherent risks 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

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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, 2008 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 $6.7 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 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.

New Accounting Standards

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement will be effective 60 days following the Securities and Exchange Commission s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not expect adoption of SFAS No. 162 to have a material impact on our consolidated financial condition, results of operations or cash flows.

In April 2008, the FASB issued FASB Staff Position (FSP) No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets . The intent of FSP 142-3 is to improve the

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consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under GAAP and SFAS No. 141(R), Business Combinations. For a recognized intangible asset, an entity shall disclose information that enables users of financial statements to assess the extent to which the expected future cash flows associated with the asset are affected by the entity s intent and/or ability to renew or extend the arrangement. FSP 142-3 is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008, with early adoption prohibited. FSP 142-3 requires the guidance for determining the useful life of a recognized intangible asset to be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements shall be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. We do not expect adoption of FSP 142-3 to have a material impact on our consolidated financial condition, results of operations or cash flows.

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). 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 do not expect adoption of SFAS No. 160 to have a material impact on our consolidated financial condition, results of operations or 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. We do not expect adoption of SFAS No. 141(R) to have a material impact on our consolidated financial condition, results of operations or 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

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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 do not expect adoption of EITF 07-01 to have a material impact on our consolidated financial condition, results of operations or cash flows.

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

As of March 2, 2009, we held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of $16.0 million and $15.5 million, respectively. 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 allowed 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, since early 2008, the banks have been allowing these auctions to fail. As a result of failed auctions, these investments now pay interest at a rate defined by the governing documents or indenture.

Our auction rate security investments are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. We do not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. We believe our investments are of high credit quality, as all are investment grade and the majority are rated AA or higher. In assessing whether declines in fair value are temporary in nature or other-than-temporary, management considers a variety of factors, including our recent history of liquidating similar instruments at par value, the length of time and extent to which the fair value has been less than par, the financial condition of the issuer and management s intent and ability to retain the investments for a sufficient period to allow for any anticipated recovery in fair value. In the fourth quarter of 2008, management determined that the $0.5 million unrealized decline in fair value of our auction rate securities was other-than-temporary. As a result, we recognized the unrealized loss in our 2008 Consolidated Statement of Operations. The determination that the loss was other-than-temporary was primarily based on the length of time that the securities have been impaired and the fact that the continuing auction failures do not enable Noven to reliably estimate when the value of the securities may recover. We will continue to monitor the market for our auction rate security investments. To the extent that future declines in fair value are determined to be other-than-temporary, additional impairment charges will result. Such non-cash impairment charges could materially and adversely affect our consolidated financial condition and results of operations.

Item 8. Financial Statements and Supplementary Data.

See Index to Consolidated Financial Statements at page 102 of this report.

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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 Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 promulgated under the Securities Exchange Act of 1934 (the Exchange Act). Based upon that evaluation, our CEO and CFO concluded that, as of December 31, 2008, 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 CEO and CFO, 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.

Scope of Management s Report on Internal Control over Financial Reporting

Management s evaluation of Noven s internal control over financial reporting at December 31, 2008 does not include an evaluation of internal control over financial reporting for Novogyne. Under the Novogyne joint venture agreements, Novartis is responsible for the financial and accounting functions at Novogyne, as well as for the establishment and maintenance of internal controls for 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 controls for Novogyne could negatively affect the financial condition and results of operations of Novogyne and Noven. Equity in earnings of Novogyne totaled $45.6 million for the year ended December 31, 2008. Our investment in Novogyne totaled $24.3 million at December 31, 2008, which represented approximately 8% of Noven s consolidated assets.

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, 2008. 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, 2008, 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 90.

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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, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, 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 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.

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In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, 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, 2008, of the Company and our report dated March 12, 2009, expressed an unqualified opinion on those consolidated financial statements.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants
Miami, FL
March 12, 2009

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Item 9B. Other Information.

Sidney Braginsky, a current member of Noven s Board of Directors, advised the Board on February 4, 2009 that he has decided to retire from the Board and that therefore he will not stand for reelection as a director at the annual meeting of stockholders to be held on May 22, 2009.

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 2009 Annual Meeting of Stockholders.

Item 11. Executive Compensation.

The information required by Item 11 is incorporated by reference to our Proxy Statement for our 2009 Annual Meeting of Stockholders.

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

The information required by Item 12 is incorporated by reference to our Proxy Statement for our 2009 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 2009 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 2009 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See Index to Consolidated Financial Statements at page 102 of this report.

(a)(2) Financial Statement Schedule

The following financial statement schedule is filed as a part of this report on page 176.

Schedule II Valuation and Qualifying Accounts for the years ended December 31, 2008, 2007 and 2006.

All other 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 By-Laws, as amended and restated as of November 18, 2008.	Incorporated by reference to Exhibit 3.1 of Noven s Form 8-K dated November 24, 2008 (File No. 0-17254).
4.1	Rights Agreement 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).
4.2	Amendment to Rights Agreement between Noven and American Stock Transfer & Trust Company dated March 18, 2008.	Incorporated by reference to Exhibit 4.1 of Noven s Form 8-K dated March 21, 2008 (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	Amended and Restated Form of Employment Agreement (Change of Control), between Noven and each of Jeffrey F. Eisenberg, Michael D. Price, Steven M. Dinh, Richard P. Gilbert, Joel S. Lippman and Anthony Venditti.*	Filed herewith.

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Exhibit Number	Description	Method of Filing
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).
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 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 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 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).

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Exhibit Number	Description	Method of Filing
10.12	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer, Inc. dated September 30, 1999 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 1999 (File No. 0-17254).
10.13	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 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).

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Exhibit Number	Description	Method of Filing
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).
10.21	License Agreement among Shire US Inc., Shire Pharmaceuticals Group PLC and Noven, dated 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 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 quarter 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	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).
10.26	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).
10.27	Form of Non-Qualified Stock Option Agreement (Non-Employee Director).*	Incorporated by reference to Exhibit 10.3 of Noven s Form 10-Q for the quarter ended September 30, 2004 (File No. 0-17254).
10.28	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).

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Exhibit Number	Description	Method of Filing
10.29	Noven Pharmaceuticals, Inc. Nonqualified Deferred Compensation Plan, as amended and restated on November 18, 2008.*	Filed herewith.
10.30	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).
10.31	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).
10.32	Agreement and Plan of Merger, dated 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).
10.33	Letter Agreement by and between Shire Pharmaceuticals Ireland Limited and Noven dated November 5, 2008.	Filed herewith.
10.34	Non-Competition Agreement between Noven and Phillip Satow, dated August 14, 2007.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated August 20, 2007 (File No. 0-17254).
10.35	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).
10.36	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).

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Exhibit Number	Description	Method of Filing
10.37	Amendment to Development, License and Supply Agreement by and between Banner Pharmacaps Inc. and Noven Therapeutics, LLC dated December 23, 2008.	Filed herewith.
10.38	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).
10.39	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).
10.40	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).
10.41	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).
10.42	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).
10.43	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).**	Incorporated by reference to Exhibit 10.48 of Noven s Form 10-K for the year ended December 31, 2007 (File No. 0-17254).
10.44	Employment Agreement between Peter Brandt and Noven, dated April 29, 2008.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated May 5, 2008 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.45	Restricted Stock Agreement between Peter Brandt and Noven, dated April 29, 2008.*	Incorporated by reference to Exhibit 10.2 of Noven s Form 8-K dated May 5, 2008 (File No. 0-17254).
10.46	Stock Appreciation Rights Agreement between Peter Brandt and Noven, dated April 29, 2008.*	Incorporated by reference to Exhibit 10.3 of Noven s Form 8-K dated May 5, 2008 (File No. 0-17254).
10.47	Amended and Restated Restricted Stock Agreement between Peter Brandt and Noven, dated May 28, 2008.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated June 2, 2008 (File No. 0-17254).
10.48	Development and License Agreement between Noven and Procter & Gamble Pharmaceuticals, Inc., dated June 30, 2008 (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, 2008 (File No. 0-17254).
10.49	Supply Agreement among Noven, Procter & Gamble Pharmaceuticals, Inc. and P&G Pharmaceuticals S.A.R.L., dated August 14, 2008 (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, 2008 (File No. 0-17254).
10.50	Credit Agreement between Noven and SunTrust Bank, dated July 31, 2008.	Incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated August 6, 2008 (File No. 0-17254).
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.

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Exhibit Number	Description	Method of Filing
31.1	Certification of Peter Brandt, President and 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.
32.1	Certification of Peter Brandt, President and 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 12, 2009

NOVEN PHARMACEUTICALS, INC.

By: /s/ Peter Brandt
Peter Brandt
President and 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/ Peter Brandt Peter Brandt President and Chief Executive Officer	Principal Executive Officer	March 12, 2009
By: /s/ Michael D. Price Michael D. Price Vice President and Chief Financial Officer	Principal Financial and Accounting Officer	March 12, 2009
By: /s/ Wayne P. Yetter Wayne P. Yetter	Chairman of the Board and Director	March 12, 2009
By: /s/ Sidney Braginsky Sidney Braginsky	Director	March 12, 2009
By: /s/ John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 12, 2009
By: /s/ Donald A. Denkhaus Donald A. Denkhaus	Director	March 12, 2009
By: /s/ Pedro P. Granadillo Pedro P. Granadillo	Director	March 12, 2009
By: /s/ Phillip M. Satow	Director	March 12, 2009

	Phillip M. Satow		
By:	/s/ Robert G. Savage	Director	March 12, 2009
	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, 2008 and 2007, 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, 2008. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of Noven s management. Our responsibility is to express an opinion on the financial statements and financial statement schedule 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, 2008, 2007, and 2006. Noven s investment in Vivelle Ventures LLC of $24,319,000 and $24,310,000 at December 31, 2008 and 2007, respectively, and Noven s share of that joint venture s income of $45,642,000, $35,850,000, and $28,632,000 for the years ended December 31, 2008, 2007, and 2006, 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, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

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, 2008, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2009, 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 12, 2009

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

	December 31, 2008	2007
Assets		
Current Assets:		
Cash and cash equivalents	$ 62,875	$ 13,973
Short-term investments available-for-sale, at fair value	3,650	21,565
Accounts receivable (less allowances of $509 at 2008 and $252 at 2007)	8,577	6,956
Accounts receivable Novogyne, net	6,510	8,683
Inventories	13,924	12,136
Net deferred income tax asset, current portion	7,026	7,614
Prepaid income taxes	8,178	4,925
Prepaid and other current assets	2,898	5,251
	113,638	81,103
Non-current Assets:		
Property, plant and equipment, net	34,886	36,213
Investments in auction rate securities	11,810	32,835
Investment in Novogyne	24,319	24,310
Net deferred income tax asset, non-current portion	65,159	58,053
Intangible assets, net	36,508	38,773
Goodwill	14,407	14,734
Deposits and other non-current assets	839	677
	187,928	205,595
	$ 301,566	$ 286,698
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,384	$ 8,399
Accrued compensation and related liabilities	7,958	9,801
Other accrued liabilities	17,260	15,270
Current portion of long-term obligations	3,396	3,421
Deferred product revenue Stavzor®	1,537	
Deferred license and contract revenues, current portion	25,459	20,188
	62,994	57,079
Non-current Liabilities:		
Long-term obligations, less current portion	27	8,438
Deferred license and contract revenues, non-current portion	77,112	85,056
Other non-current liabilities	997	1,831

	78,136	95,325
Total Liabilities	141,130	152,404
Commitments and Contingencies (Notes 7, 16 and 19)		
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; 25,235,763 and 24,881,867 issued and outstanding at December 31, 2008 and 2007	3	2
Additional paid-in capital	123,290	118,561
Retained earnings	42,267	20,855
Treasury stock, at cost 322,345 shares at December 31, 2008 and 2007	(5,124)	(5,124)
Common stock held in trust	(1,569)	(950)
Deferred compensation obligation	1,569	950
	160,436	134,294
	$ 301,566	$ 286,698

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
(amounts in thousands, except per share data)

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Product revenues Novogyne:			
Product sales, net	$ 21,308	$ 22,425	$ 19,714
Royalties	8,411	7,458	6,845
Total net product revenues Novogyne	29,719	29,883	26,559
Product revenues, net third parties	47,908	35,553	21,767
Total net product revenues	77,627	65,436	48,326
License and contract revenues	30,548	17,725	12,363
Total net revenues	108,175	83,161	60,689
Costs and Expenses:			
Cost of products sold Novogyne	15,134	13,683	14,102
Cost of products sold third parties	36,727	27,334	22,406
Total cost of products sold	51,861	41,017	36,508
Acquired in-process research and development		100,150	
Research and development	15,527	13,978	11,454
Selling and marketing	23,299	9,160	967
General and administrative	36,796	30,411	20,734
Total costs and expenses	127,483	194,716	69,663
Reversal of contingent milestone liability	5,000		
Loss from operations	(14,308)	(111,555)	(8,974)
Equity in earnings of Novogyne	45,642	35,850	28,632
Interest and other income, net	2,022	5,454	4,272
Loss on auction rate securities	(515)		
Income (loss) before income taxes	32,841	(70,251)	23,930
Provision (benefit) for income taxes	11,429	(24,875)	7,942

Net income (loss)	$ 21,412	$ (45,376)	$ 15,988
Basic earnings (loss) per share	$ 0.87	$ (1.84)	$ 0.67
Diluted earnings (loss) per share	$ 0.87	$ (1.84)	$ 0.66
Weighted average number of common shares outstanding:			
Basic	24,617	24,728	23,807
Diluted	24,729	24,728	24,252

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
(amounts in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Treasury Stock	Other	Total
Balance at December 31, 2005	23,617	$ 2	$ 89,846	$ 50,773	$	$	$ 140,621
Exercises of stock options/ SSARs	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 exercises of stock options/SSARs			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, adoption of FIN 48				(530)			(530)
Exercises of stock options/ SSARs	162		2,545				2,545
SSARs issued for non-compete agreement			265				265
Stock-based compensation expense and issuance of shares to outside directors	59		5,381				5,381
Repurchases of shares	(322)				(5,124)		(5,124)
Common stock held in trust	(27)					(575)	(575)
Deferred compensation obligation	27					575	575
Tax benefit from exercises of stock options/SSARs			458				458
Net loss				(45,376)			(45,376)
Balance at December 31, 2007	24,560	2	118,561	20,855	(5,124)		134,294
	19	1	200				201

Exercises of stock options/ SSARs							
Stock-based compensation expense and issuance of shares to outside directors	334		4,836				4,836
Tax benefit adjustments			(307)				(307)
Common stock held in trust	(45)					(619)	(619)
Deferred compensation obligation	45					619	619
Net income				21,412			21,412
Balance at December 31, 2008	24,913	$ 3	$ 123,290	$ 42,267	$ (5,124)	$	$ 160,436

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
(amounts in thousands)

	Years ended December 31,		
	2008	2007	2006
Cash flows from operating activities:			
Net income (loss)	$ 21,412	$ (45,376)	$ 15,988
Adjustments to reconcile net income (loss) to net cash flows provided by operating activities:			
Depreciation, amortization and certain other noncash items	8,994	6,762	4,340
Disposal of property, plant and equipment	656	98	89
Inventory write-offs	5,040	1,186	1,538
Reversal of contingent milestone liability	(5,000)		
Loss on auction rate securities	515		
Stock based compensation expense	4,836	5,381	3,286
Acquired in-process research and development expense		100,150	
Income tax benefits on stock-based awards/SSARs	311	458	3,556
Excess tax benefit from exercise of stock options		(370)	(2,590)
Deferred income tax benefit	(6,518)	(52,601)	(335)
Recognition of deferred license and contract revenues	(30,548)	(17,725)	(12,363)
Equity in earnings of Novogyne	(45,642)	(35,850)	(28,632)
Distributions from Novogyne	42,033	28,844	26,368
Changes in operating assets and liabilities:			
(Increase) decrease in accounts receivable trade, net	(1,621)	2,928	(27,119)
Decrease in milestone payment receivable Shire		25,000	
Decrease (increase) in accounts receivable Novogyne, net	2,173	(990)	1,219
Increase in inventories	(6,828)	(2,416)	(2,328)
Decrease in prepaid income taxes	347	4,483	6,492
Decrease (increase) in prepaid and other current assets	1,573	(2,731)	(1,053)
Increase in deposits and other assets	(255)		(15)
Decrease in accounts payable and accrued expenses	(776)	(3,743)	(6,116)
(Decrease) increase in accrued compensation and related liabilities	(1,806)	3,121	(463)
Increase (decrease) in other accrued liabilities	1,106	4,716	(39)
Increase in deferred license and contract revenues	27,875	32,125	78,012
Increase in deferred product revenue Stavzor®	1,537		
Increase in other liabilities	183	919	192
Cash flows provided by operating activities	19,597	54,369	60,027
Cash flows from investing activities:			
Purchases of property, plant and equipment	(3,820)	(2,753)	(6,261)
Payments for intangible assets	(1,997)	(181)	(616)
Acquisition of JDS, net of cash acquired		(130,360)	
Purchase of company-owned life insurance	(335)	(260)	(185)
Purchases of investments	(62,800)	(1,568,598)	(1,298,424)
Proceeds from sale of investments	101,225	1,658,653	1,171,975

Cash flows provided by (used in) investing activities	32,273	(43,499)	(133,511)
Cash flows from financing activities:			
Issuance of common stock from exercise of stock options/SSARs	201	2,545	13,224
Purchase of treasury stock		(5,124)	
Excess tax benefit from exercise of stock options		370	2,590
Payments of long-term obligations	(3,169)	(3,832)	(150)
Cash flows (used in) provided by financing activities	(2,968)	(6,041)	15,664
Net increase (decrease) in cash and cash equivalents	48,902	4,829	(57,820)
Cash and cash equivalents, beginning of year	13,973	9,144	66,964
Cash and cash equivalents, end of year	$ 62,875	$ 13,973	$ 9,144

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, manufacturing, licensing, marketing and sale of prescription pharmaceutical products.

Noven and Novartis Pharmaceuticals Corporation (Novartis) established 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® and CombiPatch®.

On August 14, 2007 (the Closing Date), Noven acquired Noven Therapeutics, LLC (f/k/a JDS Pharmaceuticals, LLC (JDS)), a privately-held specialty pharmaceutical company that currently markets and sells three branded prescription psychiatry products through a targeted sales force. In connection with the acquisition, Noven also acquired a product pipeline which included Mesafem , a developmental non-hormonal product for vasomotor symptoms (hot flashes), and Noven is advancing the clinical development of Mesafem . Noven accounted for the acquisition of Noven Therapeutics using the purchase method of accounting and the results of operations of Noven Therapeutics have been included in Noven s consolidated results beginning on the Closing Date (see Note 4 Acquisition of Noven Therapeutics, LLC).

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 under the equity method of accounting 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:

Noven operates in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, the women s health joint venture between Noven and Novartis in which Noven owns a 49% equity interest; and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products. Historically, Novogyne was viewed as a component of the Noven Transdermals unit because the joint venture s primary activity involves the marketing and sale in the United States and Canada of patches manufactured by Noven Transdermals. In the fourth quarter of 2008, as a result of management and organizational changes throughout

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2008, Noven revised its presentation of reportable segments to reflect the joint venture as a reportable unit distinct from the manufacturing and licensing activities of Noven Transdermals. This view is consistent with the manner in which information is reported for management decision making. See Note 17 Segment and Customer Data for Noven s segment financial reporting.

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; (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) determining 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) the allocation of purchase price to acquired assets including identifiable intangibles and goodwill; (vi) determination of the economic lives of intangible assets; (vii) estimates of cash flows used to assess the recoverability and fair values of intangible assets and goodwill; (viii) determination of the net realizable value of the net deferred tax asset, estimation of the effective tax rate and income and other tax accruals; and (ix) valuation of auction rate securities.

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, 2008 and 2007, 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 auction rate securities, which are classified as available-for-sale under the provisions of Statement of Financial Accounting Standards (SFAS) No. 115 Accounting for Certain Investments in Debt and Equity Securities (SFAS No. 115). In

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accordance with SFAS No. 115, these investments are reported in the Consolidated Balance Sheets at fair value. Any unrealized gains and losses deemed to be of a temporary nature are included in comprehensive income (loss) as a separate component of stockholders equity, net of applicable taxes. Unrealized losses determined to represent other-than-temporary declines in fair value are charged to operations in the period such determination is made.

As of December 31, 2008 and 2007, Noven s investments in securities, which are classified as available-for-sale, consisted of the following (amounts in thousands):

	Fair Value December 31,	
	2008	2007
Tax-exempt variable rate demand bonds	$	$ 4,000
Tax-exempt auction rate securities	3,650	17,565
Investments, current	3,650	21,565
Tax-exempt auction rate securities, non-current	11,810	32,835
Total investments in securities	$ 15,460	$ 54,400

As further discussed in Note 19, Commitments and Contingencies Credit Facility, in connection with the $15.0 million credit facility obtained in July 2008, Noven agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of Noven s financial assets, including its investments in auction rate securities.

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 expense all inventory purchased for research and development purposes.

During 2008, Noven recorded a $5.0 million charge to cost of products sold related to the write-off of inventories. These write-offs were primarily related to an equipment failure in transdermal manufacturing during the three months ended March 31, 2008 which resulted in

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$1.8 million of write-offs of products manufactured for Novogyne and $1.0 million of third party HT product write-offs, as well as inventory write-offs during 2008 of approximately $1.5 million due to Daytrana® product and $0.7 million related to scrap and expired material in the ordinary course of business.

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 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. Amounts paid by Shire to Noven for exceeding such yield requirements for 2008 and 2007 were not material. During 2008 and 2007, Noven used $5.7 million and $5.9 million of Shire s AMI in the finished product, respectively, and had $2.6 million of Shire s consignment AMI inventory on hand at December 31, 2008 and 2007, 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, 2008 and 2007 (amounts in thousands):

	2008	2007
Finished goods	$ 3,200	$ 3,171
Work in process	2,510	1,532
Raw materials	8,214	7,433
	$ 13,924	$ 12,136

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, 2008 and 2007 (dollar amounts in thousands):

	2008	2007	Estimated Useful Lives (in years)
Land	$ 2,540	$ 2,540	
Building and improvements	3,279	3,416	40
Leased property and leasehold improvements	22,111	22,400	10-31
Manufacturing and other equipment	22,992	26,181	3-10
Furniture	2,017	2,628	10
Software and software development costs	6,657	5,141	3
	59,596	62,306	
Less accumulated depreciation and amortization	(24,710)	(26,093)	
	$ 34,886	$ 36,213	

Property, plant and equipment are recorded at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets ranging up to 40 years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the improvements. Major renewals and betterments are capitalized, while maintenance repairs and minor renewals are expensed as incurred. During 2008, 2007 and 2006, depreciation expense totaled $4.3 million, $4.4 million and $4.0 million, respectively. During 2008, property, plant and equipment were retired, which had an original cost of $6.3 million and a net book value of $0.7 million.

IMPAIRMENT OF LONG-LIVED ASSETS:

Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. When factors indicate that an asset should be evaluated for possible impairment, Noven reviews such long-lived asset to assess recoverability from future operations using undiscounted cash flows. If it is determined that an asset s carrying value will not be recovered through operations, then an impairment would be recognized in earnings to the extent that carrying value exceeds fair value. 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.

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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. In accordance with SFAS No. 141, Business Combinations, which applied to acquisitions prior to January 1, 2009, the cost to acquire a business, including transaction costs, was 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 were charged to operations at the date of acquisition (see Note 4 Acquisition of Noven Therapeutics, LLC). Acquisitions completed after December 31, 2008 will be accounted for accordance with SFAS No. 141 (R), Business Combinations . Under SFAS No. 141 (R), assets used in research and development activities will be initially recognized and measured at fair value and transaction costs will be charged to operations rather than being included as a component of the purchase price. Under either approach, finite-lived 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 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 Noven Therapeutics, in addition to the value of acquired tangible assets and assumed liabilities, Noven ultimately recorded on its balance sheet $39.1 million of identifiable intangible assets and $14.4 million of goodwill.

All of Noven s goodwill arose from the Noven Therapeutics acquisition in August 2007 and, thus, relates to the Noven Therapeutics segment. Goodwill is tested for impairment annually in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying value of 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. Noven s finite-lived intangible assets are evaluated for impairment whenever events or circumstances indicate that the carrying amounts may not be 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, 2008, Noven determined that no impairment of goodwill or intangible assets existed.

PATENT DEVELOPMENT COSTS:

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

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INCOME TAXES:

Income taxes have been accounted 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 FASB Interpretation No. (FIN) 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 income 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. The impact of the adoption of FIN 48 is described in Note 16 Income Taxes .

COMMITMENTS AND CONTINGENCIES:

Noven accounts for commitments and contingencies in accordance with the provisions of SFAS No. 5, Accounting for Contingencies (SFAS No. 5). SFAS No. 5 provides that accruals are to be established for contingencies that are probable and estimable. However, estimating the amount to accrue usually requires significant judgment. See Note 7 Contract and License Agreements , Note 16 Income Taxes and Note 19 Commitments and Contingencies for furth information.

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), and Shire. All of Noven Therapeutics product revenues relate to the commercial sale

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of its three FDA-approved products, Stavzor®, Pexeva® and Lithobid®. 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 sets forth a minimum supply price per unit that Noven is entitled to receive from the licensee. 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.

Product revenues include royalty revenues consisting of royalties payable by Novogyne and Novartis Pharma on sales of Vivelle-Dot®/Estradot® in the United States and Canada. Noven accrues royalty revenues and the related receivables each quarter based on Novogyne s and Novartis Pharma s net sales for that quarter.

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.

In July 2008, the United States Food and Drug Administration (FDA) granted final approval for Stavzor® (valproic acid delayed release capsules) for the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. In the third quarter of 2008, Noven made a $1.5 million milestone payment to Banner Pharmacaps Inc. (Banner) upon receiving FDA approval for Stavzor®. Upfront and milestone payments made to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred. Payments made to third parties subsequent to regulatory approval are capitalized and amortized through cost of products sold over the shorter of the period over which the economic benefit is expected to be realized or their remaining legal lives. Noven Therapeutics commercially launched Stavzor® in August 2008. Noven sells Stavzor® to pharmaceutical wholesalers and chain drug stores. These companies have the right to return Stavzor® for up to one year after product expiration. As a result of the commercial launch of Stavzor® in the third quarter of 2008, Noven does not have sufficient sales history to reasonably estimate product returns. Under SFAS No. 48, Revenue Recognition When Right of Return Exists (SFAS No. 48), Noven cannot recognize revenue on product shipments until it can reasonably estimate returns relating to these shipments. In accordance with SFAS No. 48, Noven defers recognition of revenue and the associated costs on product shipments of Stavzor® to Noven s customers until such time as Stavzor® units are dispensed through patient prescriptions, because Noven s customers are no longer permitted to return the product after it has been dispensed. Noven estimates the volume of prescription units dispensed at pharmacies based on data provided by external sources. These sources poll pharmacies, hospitals, mail order and other retail outlets for Stavzor® prescriptions and project this sample on a national level. Noven will recognize revenue based on prescription units dispensed until Noven has sufficient sales history to reasonably estimate its product returns. Noven recognized $0.4 million of net revenues for Stavzor® in 2008 and $1.5 million remained in deferred product revenue on Noven s Consolidated Balance Sheet as of December 31, 2008.

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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. 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. Management believes that the sales allowances are reasonably determinable and are based on the information available at that time to arrive at its best estimate.

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 included in the Consolidated Balance Sheets as of December 31, 2008 and December 31, 2007, were as follows (amounts in thousands):

	2008	2007
Accounts receivable:		
Gross receivable	$ 9,086	$ 7,208
Sales allowances and allowances for doubtful accounts	(509)	(252)
Accounts receivable, net	$ 8,577	$ 6,956
Sales allowances:		
Accrued Medicaid, Medicare, State programs and other rebates	$ 2,726	$ 4,065
Allowance for product returns	3,070	1,875
Other sales allowances	594	770
Total sales allowances	$ 6,390	$ 6,710

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License Revenues and Multiple Element Arrangements

License revenues consist of the recognition of non-refundable 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 (EITF Issue 00-21), 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, giving particular consideration to the manner in which the customer receives the benefit of the transaction.

In general, revenues from non-refundable, 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. Historically, we have applied the guidance of EITF Issue 00-21, and have typically 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 non-refundable 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 Noven has fulfilled all of its obligations relating 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 period over which to recognize license revenues, Noven considers the remaining life of proprietary protection and the economic lives of competing products in the specific or similar therapeutic categories as a basis for estimating 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

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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 non-refundable 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.

Shire Collaboration Daytrana®

In 2003, Noven entered into a collaborative agreement with Shire 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. Noven determined that the arrangement included three deliverables: (i) a license; (ii) a research and development arrangement; and (iii) a manufacturing and supply agreement.

The license and research and development deliverables did not meet the criteria for separation under EITF Issue 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 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 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. In Noven s collaboration with Shire, Noven receives 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

As described in Note 7 Contract and License Agreements, in November 2008, Noven and Shire terminated a 2004 agreement for the development of an amphetamine patch to treat ADHD. As a result of the termination, Noven recognized $7.2 million as license and contract revenues in 2008 for non-refundable amounts which had previously been received and deferred.

Contract Revenues

Contract revenues consist of the recognition of contract payments related to research and development projects performed for third parties where Noven has determined that such projects are separate 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 in the following forms for the research and development work performed:

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non-refundable 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.

Noven recognizes revenue from non-refundable up-front payments based on the proportional performance method as Noven performs the agreed research and development work. Contractual amounts received upon completion of specified 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.

RESEARCH AND DEVELOPMENT COSTS:

Research and development expenses include costs of internally generated research and development activities and costs associated with work performed under agreements with third parties. Research and development expenses 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 for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel costs associated with each of these functions.

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 and marketing 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 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, 2008, 2007 and 2006 were 3.3 million, 1.7 million and 0.4 million 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, 0.4 million in-the-money options and/or stock settled appreciation rights were excluded from the diluted loss per share calculation for 2007 as their effect would have been antidilutive.

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COMPREHENSIVE INCOME (LOSS):

For the years ended December 31, 2008, 2007 and 2006, comprehensive income (loss) was equal to net income (loss). In the first quarter of 2008, Noven recognized a $0.5 million temporary unrealized loss on its investments in auction rate securities through other comprehensive loss. As discussed in Note 5 Investments Available-for-Sale, in the fourth quarter of 2008, management determined that the loss was other-than-temporary and, accordingly, recognized the loss in the 2008 Consolidated Statement of Operations.

EQUITY 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 uses the Black-Scholes option pricing model to determine the fair value of stock options and stock-settled stock appreciation rights (SSARs). The grant date fair value of stock-based payment awards is determined using an option-pricing model which considers Noven s stock price, as well as a number of complex and subjective variables, including Noven s expected stock price volatility over the expected term of the awards, expected exercise behavior, risk-free interest rate, estimated forfeitures and expected dividends.

The expected term of stock options/SSARs is defined as the expected time that options will remain outstanding assuming they are not forfeited prior to the vest date. Noven estimates the expected term using a statistical predictive model that incorporates Noven s historical exercise activity in conjunction with Noven s post-vest termination information. 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. The risk-free interest rate is based 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. The weighted average grant date fair values of options/SSARs granted during 2008, 2007 and 2006 were $4.94, $6.67 and $10.94, respectively, using the Black-Scholes option-pricing model with the assumptions below:

	Years Ended December 31,		
	2008	2007	2006
Volatility	52.3%	48.5%	49.2%
Risk free interest rate	2.67%	3.90%	4.67%
Expected life (years)	5	5	5
Dividend yield	0%	0%	0%

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Total stock-based compensation recognized in Noven s Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006 were as follows (amounts in thousands):

	2008	2007	2006
Selling and marketing	$ 552	$ 357	$ 415
General and administrative	3,346	4,165	2,043
Research and development	473	543	412
Total cost of products sold	465	316	416
	$ 4,836	$ 5,381	$ 3,286
Tax benefit recognized related to compensation expense	$ 1,688	$ 1,861	$ 941

In accordance with SFAS No. 123(R), tax benefits at the time of exercise in excess of those recognized in conjunction with compensation expense are reported as cash flow from financing activities. Cash received from options exercised under all share-based payment arrangements for the years ended December 31, 2008, 2007 and 2006 was $0.2 million, $2.5 million and $13.2 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements for 2008 was $0.3 million. In addition, Noven recognized $0.3 million of tax benefit adjustments resulting from exercises and terminations of vested awards in 2008. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled $0.5 million and $3.6 million for the years ended December 31, 2007 and 2006, respectively, of which $0.4 million and $2.6 million was reported as a cash inflow from financing activities for the years ended December 31, 2007 and 2006, respectively. The total intrinsic values of all option exercises for the year ended December 31, 2008 were not material. The total intrinsic values of all option exercises for the years ended December 31, 2007 and 2006 were $1.6 million and $10.5 million, respectively.

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 were 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 units awarded to the former chief executive officer.

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.

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Noven maintains an allowance for doubtful accounts based on an assessment of the collectability of such accounts. See Note 17 Segment and Customer Data for information on revenues by customer.

RECENT ACCOUNTING PRONOUNCEMENTS:

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement will be effective 60 days following the Securities Exchange and Commission s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. Noven does not expect adoption of SFAS No. 162 to have a material impact on its consolidated financial condition, results of operations or cash flows.

In April 2008, the FASB issued FASB Staff Position (FSP) No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets . The intent of FSP 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under GAAP and SFAS No. 141(R), Business Combinations. For a recognized intangible asset, an entity shall disclose information that enables users of financial statements to assess the extent to which the expected future cash flows associated with the asset are affected by the entity s intent and/or ability to renew or extend the arrangement. FSP 142-3 is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008, with early adoption prohibited. FSP 142-3 requires the guidance for determining the useful life of a recognized intangible asset to be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements shall be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. Noven does not expect adoption of FSP 142-3 to have a material impact on its consolidated financial condition, results of operations or cash flows.

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). 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. Noven does not expect adoption of SFAS No. 160 to have a material impact on its consolidated financial condition, results of operations or cash flows.

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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 does not expect adoption of SFAS No. 141 (R) to have a material impact on its consolidated financial condition, results of operations or 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. Noven does not expect adoption of EITF 07-01 to have a material impact on its consolidated financial condition, results of operations or cash flows.

RECLASSIFICATIONS:

Certain reclassifications have been made to the prior periods Consolidated Statements of Operations and Consolidated Statements of Cash Flows to conform to the current period s presentation.

3. CASH FLOW INFORMATION:

Cash payments for income taxes were $20.8 million, $23.7 million and $0.8 million in 2008, 2007 and 2006, respectively. In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. In 2008, 2007 and 2006, Novogyne paid $3.6 million, $6.0 million and $2.2 million, respectively, to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state income tax payment. These payments were deemed distributions to Noven from Novogyne. Noven received tax refunds directly from the State of New Jersey of $2.7 million, $2.4 million and $1.9 million in 2008, 2007 and 2006, respectively, related to these state income tax payments made on Noven s behalf. Cash payments for interest were not material in 2008, 2007 and 2006.

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Non-cash Operating Activities

The income tax benefit from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options was $0.3 million for 2008. Noven recorded a $0.5 million and $3.6 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 and 2006, 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.

Noven did not enter into capital lease obligations in 2008. In 2007 and 2006, Noven entered into capital lease obligations for new equipment totaling $0.1 million and $0.4 million, respectively.

4. ACQUISITION OF NOVEN THERAPEUTICS, LLC:

Noven acquired Noven Therapeutics, LLC (f/k/a JDS Pharmaceuticals, LLC) on August 14, 2007 pursuant to the terms of the Agreement and Plan of Merger, dated July 9, 2007. The purchase price for the acquisition was $125.0 million cash paid at closing, subject to certain working capital adjustments (the Merger Consideration). Noven funded the cash purchase price from the sale of short-term investments. 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. The working capital adjustments were finalized in June 2008, resulting in a $1.1 million payment to Noven from the escrow account. The balance of the escrowed funds was disbursed to the sellers in January 2009.

The total purchase price for the Noven Therapeutics 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, approximately $0.5 million in connection with non-competition agreements entered into with two executives of JDS and $1.0 million of net working capital adjustments. 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.

In addition to the non-competition agreements which were included in the purchase price, the Company also entered into a one-year agreement with the JDS CEO to provide consulting services with respect to Noven Therapeutics business as may reasonably be requested

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by Noven in exchange for a service fee of $250 per hour. Noven paid the former JDS CEO $50,500 and $37,500 under the consulting agreement which was charged to operations in 2008 and 2007, respectively. 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 was charged to operations during 2008.

The acquisition of Noven Therapeutics 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. In 2008, the purchase price allocation was completed, resulting in a final goodwill value of $14.4 million (see Note 9 Goodwill and Intangible Assets). The primary factors that contributed to the recognition of goodwill 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 final allocation of the total purchase price for the acquisition of Noven Therapeutics (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	39,110
Goodwill	14,407
Other assets	163
Accrued expenses and other current liabilities	(15,330)
Long-term obligation assumed	(3,711)
Contingent milestones assumed	(11,500)
Total purchase price	$ 131,919

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

IPR&D is defined by FIN 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 following the completion of the acquisition and is reflected in Noven s Consolidated Statement of Operations for the year ended December 31, 2007.

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The fair value of IPR&D has been determined by the income approach using the multi-period excess earnings method on a project-by-project basis. The projects were valued based on the present value of probability adjusted incremental cash flows, after deducting 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.

Identifiable Intangible Assets

The identifiable intangible assets acquired are attributable to the following categories based on the final purchase price allocation (dollar amounts in thousands):

	Fair Value	Asset life (years)
Acquired product intangibles	$ 37,790	6 - 10
Non-competition agreements	530	2 - 3
Favorable lease	790	2
Total identifiable intangible assets	$ 39,110	

Intellectual Property approved products

The fair value of the intellectual property rights (including technical processes and institutional understanding) associated with Noven Therapeutics products approved by the FDA has been determined by the income approach

using the multi-period excess earnings method.

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This method calculates fair value 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) in generating the cash flows. 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, which applied to acquisitions prior to January 1, 2009, 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 with a fair value of $3.7 million on the Closing Date. The long-term obligation was paid in full by Noven in 2007. Noven also assumed $11.5 million of future contingent sales milestones related to Noven Therapeutics 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, which applied to acquisitions prior to January 1, 2009, the contingent sales milestones were recorded as liabilities in the amount of $11.5 million. In the third quarter of 2008, management determined that the likelihood of paying $5.0 million of such milestones was no longer probable. As a result, Noven reversed the liability. Because the purchase allocation with regard to this item had been finalized, Noven recognized $5.0 million in operating income as a result of the reversal. See Note 7 Contract and License Agreements Synthon Pharmaceuticals Collaboration for further information about the contingent sales milestones.

Supplemental disclosure of pro forma information

The following represents Noven s pro forma results of operations as though the acquisition of Noven Therapeutics 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.

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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. INVESTMENTS AVAILABLE-FOR-SALE:

At December 31, 2008, Noven held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of $16.0 million and $15.5 million, respectively. Noven liquidated $39.0 million of its investments in auction rate securities at par value during 2008. An additional $3.7 million has been called by the issuer and is expected to be redeemed in March 2009. 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. 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. As a result of failed auctions, these investments now pay interest at a rate defined by the governing documents or indenture. Due to uncertainty regarding the timing of Noven s future investment liquidations, Noven classified its auction rate securities as non-current assets as of December 31, 2008, except for the called security, which is included in current assets.

Noven s auction rate security investments are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. Noven does not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. Noven believes its investments are of high credit quality, as all are investment grade and the majority are rated AA or higher. In assessing whether declines in fair value are temporary in nature or other- than-temporary, management considers a variety of factors, including Noven s recent history of liquidating similar instruments at par value, the length of time and extent to which the fair value has been less than par, the financial condition of the issuer and management s intent and ability to retain the investments for a sufficient period to allow for any anticipated recovery in fair value. In the fourth quarter of 2008, Noven determined that the $0.5 million unrealized decline in fair value of its auction rate portfolio was other-than-temporary. As a result, Noven recognized the impairments in its 2008 Consolidated Statement of Operations. The determination that the unrealized losses were other-than-temporary was primarily based on the length of time that the securities have been impaired and the fact that the continuing auction failures do not enable Noven to reliably estimate when the value of the securities may recover. To the extent future declines in fair value are determined to be other-than-temporary, additional impairment charges will result. Such non-cash impairment charges could materially and adversely affect Noven s consolidated financial condition and results of operations.

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6. FAIR VALUE MEASUREMENTS:

Noven adopted SFAS No. 157, Fair Value Measurements in 2008. SFAS No. 157, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. SFAS No. 157 clarifies that fair value is an exit price, representing the amount expected to be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. To increase consistency and comparability in fair value measurements and related disclosures, SFAS No. 157 sets forth a three-tier hierarchy for the inputs used to measure fair value based on the degree to which such inputs are observable in the marketplace, as follows:

(i) Level 1 observable inputs such as quoted prices in active markets;

(ii) Level 2 inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

(iii) Level 3 unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

As described in Note 5 Investments Available-for-Sale, during 2008, Noven recorded $0.5 million of other-than-temporary impairments on its investments in auction rate securities which are classified as available-for-sale under SFAS No. 115. Due to continuing auction failures beginning in February 2008, Noven utilized valuation models to determine the fair values of its investments in auction rate securities. The fair values of the investments were calculated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

Changes to investments measured at fair value on a recurring basis using unobservable inputs (Level 3) during 2008 were as follows (in thousands):

Balance at December 31, 2007	$ 54,400
Purchases of investments	550
Sales of investments at par	(38,975)
Unrealized losses, other-than-temporary	(515)
Balance at December 31, 2008	$ 15,460

7. 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 or expiration of Noven s license agreement with Aventis. This lease includes an option to purchase the leased facilities and property for its depreciated value and subsequent to year-end, Noven began the process of exercising this option and purchasing the facilities and properties for $1.00, its depreciated value as of December 31, 2008. 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, 2008 and 2007, the carrying amounts of the leased property and deferred revenues were $3.4 million and $3.6 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.

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 this licensing transaction, Shire agreed to pay Noven as follows: (i) $25.0 million was paid upon closing of the transaction in April 2003; (ii) $50.0 million was paid in April 2006 upon receipt of final marketing approval by the FDA; and (iii) three installments of $25.0 million each payable upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual Daytrana® net sales, respectively. Noven received the first $25.0 million sales milestone in the first quarter of 2007, the second $25.0 million sales milestone in the third quarter of 2007 and the third $25.0 million sales milestone in the third quarter of 2008. Noven is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is Noven s current best estimate of the end of the useful economic life of the product. During 2008, 2007 and 2006 Noven recognized $18.8 million, $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 2008, 2007 and 2006 Noven s product sales of Daytrana® to Shire were $10.8 million, $13.4 million and $8.6 million, respectively.

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 first $25.0 million sales milestone received from Shire. The reimbursements to Shire reduced the amount of deferred revenues that Noven is currently recognizing related to the original $25.0 million up-front payment.

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

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amended agreement, Shire paid Noven $6.9 million for the exclusive developmental rights to the product. A total of $7.2 million received under the amphetamine arrangement was included in deferred license and contract revenues on Noven s Consolidated Balance Sheet as of December 31, 2007. Noven entered into a letter agreement (the Termination Agreement) with Shire terminating Noven s agreements with Shire for the development of an amphetamine patch. Under the Termination Agreement, rights to the developmental amphetamine patch were returned to Noven. Noven currently intends to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if Noven elects to commercialize a product that incorporates intellectual property arising from the development project with Shire. As a result of the termination of this project with Shire, Noven recognized $7.2 million as license and contract revenues in the fourth quarter of 2008.

P&G PHARMACEUTICALS COLLABORATION

In April 2003, Noven established a collaboration with Procter & Gamble Pharmaceuticals, Inc. (P&GP) relating to the development and commercialization of prescription transdermal patches for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in women. The products under development explore follow-on product opportunities for Intrinsa®, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore sexual desire in menopausal women diagnosed with HSDD. Until recently, P&GP had indicated that the project was on hold.

In August 2008, Noven entered into global license and supply agreements with P&GP relating to the development and commercialization of prescription transdermal patches for the treatment of HSDD and other indications in women. The global license agreement supersedes and replaces the prior development letter agreement entered into between Noven and P&GP on April 28, 2003. Under the agreements, Noven granted P&GP an exclusive worldwide license to our low-dose testosterone patch for use by women for HSDD and other indications, as well as potential next-generation patches, and P&GP granted Noven exclusive supplier rights with respect to such licensed products. Noven received a $1.0 million payment from P&GP upon entering into the agreement, and has included the amount in deferred license and contract revenues on its Consolidated Balance Sheet as of December 31, 2008. If the testosterone patch is ultimately approved and commercially launched, Noven would receive royalties and manufacturing fees under the agreements. Noven may also receive additional contingent development and sales milestone payments related to the licensed products. The royalty payments are to be determined based on a percentage of P&GP s quarterly sales of the licensed products. The milestone payments are contingent upon the achievement of certain sales milestones. Pursuant to the agreements, P&GP will fund any clinical development costs and will be responsible for any regulatory filings and marketing applications associated with any licensed products developed under the agreements.

SYNTHON PHARMACEUTICALS COLLABORATION

In November 2005, JDS, now known as Noven Therapeutics, entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc. (Synthon) for the purchase of Pexeva®. In this transaction, Noven Therapeutics 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.

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As a result of Noven s acquisition of Noven Therapeutics, Noven became responsible for possible future contingent milestone payments of up to $11.5 million in the event sales of Pexeva® achieve certain levels under the asset purchase agreement with Synthon. Based on net sales of Pexeva® in 2007 and 2008, Noven Therapeutics was required to make milestone payments to Synthon of $3.3 million for each of those years. The 2007 milestone was paid in April 2008 and the 2008 milestone is expected to be paid in April 2009.

Noven accrued for these contingent milestone payments at the time of closing of the Noven Therapeutics acquisition based on projected future sales of Pexeva® which indicated that the achievement of each of the specified sales levels was probable. In the third quarter of 2008, Noven determined that the achievement of $30.0 million in annual net sales for Pexeva®, the next specified sales level, was no longer probable, resulting in a change in accounting estimate. The change results from lower forecasted long-term prescription growth than originally expected, as well as a redistribution of selling effort to support Stavzor®, which was commercially launched in August 2008. In the third quarter of 2008, Noven recognized $5.0 million in operating income as a result of the reversal of the accrued liability for the final contingent milestone payment upon a determination that the achievement of the milestone was no longer probable. The change in accounting estimate resulted in a positive net income impact of $3.1 million after taxes for 2008. Although Noven reversed the $5.0 million accrued liability, Noven remains contingently liable for the $5.0 million payment if annual net sales of a future product utilizing the same compound as is used in Pexeva® achieves sales of $30.0 million or more through 2017.

SOLVAY PHARMACEUTICALS COLLABORATION

In August 2004, Noven Therapeutics entered into an asset purchase agreement with Solvay Pharmaceuticals, Inc. (Solvay) for the purchase of Lithobid®. In this transaction, Noven Therapeutics 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 the Merger. In connection with the acquisition of the product rights for Lithobid®, Noven Therapeutics 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 Noven Therapeutics, Solvay assigned the manufacturing and supply agreement to ANI Pharmaceuticals, Inc. (ANI). In December 2007, Noven Therapeutics 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.

BANNER PHARMACAPS COLLABORATION

In April 2007, Noven Therapeutics 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.

In September 2008, Noven made a $1.5 million milestone payment to Banner upon FDA approval for Stavzor®. The remaining potential development milestone payments of up to $4.5 million were contingent upon the satisfaction of certain conditions related to the development

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of an extended release valproic acid product. In December 2008, Noven and Banner agreed to terminate the development of an extended release product, and Noven paid Banner $250,000 in connection with the termination to reimburse Banner for development costs incurred on the project. The payment was charged to operations in 2008.

OTHER AGREEMENTS

Noven has entered into other developmental agreements for feasibility testing of certain compounds. Noven received approximately $0.8 million in each of 2008 and 2007 and $0.2 million in 2006 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.

8. 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 7 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, 2008, 2007 and 2006 are as follows (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Gross revenues	$ 197,994	$ 171,347	$ 154,901
Sales allowances	23,731	21,912	17,226
Sales returns allowances	4,645	1,447	5,732
Sales allowances and returns	28,376	23,359	22,958
Net revenues	169,618	147,988	131,943
Cost of sales	33,795	31,203	30,149
Selling, general and administrative expenses	37,471	38,084	37,319
Income from operations	98,352	78,701	64,475
Interest income and other	1,129	1,145	842
Net income	$ 99,481	$ 79,846	$ 65,317
Noven s equity in earnings of Novogyne	$ 45,642	$ 35,850	$ 28,632

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The activity in the Investment in Novogyne account for the years ended December 31, 2008, 2007 and 2006 is as follows (amounts in thousands):

	2008	2007	2006
Investment in Novogyne, beginning of period	$ 24,310	$ 23,296	$ 23,243
Equity in earnings of Novogyne	45,642	35,850	28,632
Cash distributions from Novogyne	(42,033)	(28,844)	(26,368)
Deemed distribution by Novogyne for state income tax payment	(3,600)	(5,992)	(2,211)
Investment in Novogyne, end of period	$ 24,319	$ 24,310	$ 23,296

Subject to the approval of Novogyne s management committee, Novogyne may, from time to time, distribute cash to Novartis and Noven based upon a contractual formula. The joint venture agreements provide for an annual preferred return of $6.1 million to Novartis and then an allocation of income between Novartis and Noven depending upon sales levels attained. Noven s share of Novogyne s earnings increases as Novogyne s product sales increase, subject to a cap of 49%. In addition, as discussed in Note 3 Cash Flow Information , tax payments of $3.6 million, $6.0 million and $2.2 million were made by Novogyne on Noven s behalf to the New Jersey Department of Revenue in 2008, 2007 and 2006, respectively. These amounts were recorded as reductions in the investment in Novogyne when received (or in the case of tax payments, when paid).

The summarized Balance Sheets of Novogyne at December 31, 2008 and 2007 are as follows (amounts in thousands):

	December 31,	
	2008	2007
Current assets	$ 41,956	$ 36,994
Insurance receivable	6,663	6,484
Intangible assets	13,904	20,083
Total assets	$ 62,523	$ 63,561
Product liability reserve	9,034	8,976
Allowance for returns	7,215	6,036
Other liabilities	7,696	10,174
Total liabilities (all of which are current)	23,945	25,186
Members capital	$ 38,578	$ 38,375

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The activity for the allowance for returns for the years ended December 31, 2007 and 2008 is as follows (amounts in thousands):

	2008	2007
Balance, beginning of year	$ 6,036	$ 7,938
Expense related to expired product-current year	3,982	3,372
Revision to prior year expense estimate	663	(1,925)
Deductions	(3,466)	(3,349)
Balance, end of year	$ 7,215	$ 6,036

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.

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During the years ended December 31, 2008, 2007 and 2006, Noven had the following transactions with Novogyne (amounts in thousands):

	2008	2007	2006
Revenues:			
Trade product	$ 18,277	$ 18,576	$ 17,013
Sample product and other	3,031	3,849	2,701
Royalties	8,411	7,458	6,845
	$ 29,719	$ 29,883	$ 26,559
Reimbursed expenses:			
Services	$ 23,234	$ 21,771	$ 20,926
Product specific marketing expenses	5,719	7,402	7,850
Reimbursed expenses	$ 28,953	$ 29,173	$ 28,776

Reimbursed expenses are primarily comprised of selling and marketing expenses paid by Noven on behalf of Novogyne. As of December 31, 2008 and December 31, 2007, Noven had amounts due from Novogyne of $6.5 million and $8.7 million, respectively.

As of December 31, 2008 and 2007, the Accounts Receivable Novogyne, net is as follows (amounts in thousands):

	2008	2007
Sales of product	$ 2,577	$ 4,600
Services provided by Noven	3,239	3,710
Royalties	1,627	1,694
Deferred profit on Novogyne inventory and other	(933)	(1,321)
	$ 6,510	$ 8,683

9. GOODWILL AND INTANGIBLE ASSETS:

All of Noven s goodwill arose from the Noven Therapeutics acquisition in August 2007 and, thus, relates to the Noven Therapeutics segment. The carrying amount of goodwill is $14.4 million and $14.7 million at December 31, 2008 and December 31, 2007, respectively. In 2008, Noven finalized the purchase price allocation related to the Noven Therapeutics acquisition, resulting in a $0.3 million net reduction in goodwill.

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Noven s intangible assets, all of which are subject to amortization, are summarized in the tables below as of December 31, 2008 and December 31, 2007 (amounts in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (years)
As of December 31, 2008				
Patent development costs	$ 4,929	$ (3,070)	$ 1,859	7.2
Acquired product intangibles	39,290	(5,289)	34,001	9.0
Non-competition agreements	530	(304)	226	1.6
Favorable lease	790	(368)	422	2.0
	$ 45,539	$ (9,031)	$ 36,508	8.0
As of December 31, 2007				
Patent development costs	$ 4,542	$ (2,573)	$ 1,969	8.1
Acquired product intangibles	37,790	(1,549)	36,241	10.0
Non-competition agreements	530	(82)	448	2.4
Favorable lease	227	(112)	115	0.8
	$ 43,089	$ (4,316)	$ 38,773	9.8

The intangible assets for acquired products, non-competition agreements and favorable lease included in the tables above resulted primarily from the Noven Therapeutics acquisition. In addition, in the third quarter of 2008, Noven made a $1.5 million milestone payment to Banner upon FDA approval for Stavzor®. The payment was included in acquired product intangibles and is being amortized over the estimated life of the product. Amortization expense was $4.7 million, $2.3 million and $0.5 million for 2008, 2007 and 2006, respectively.

Noven estimates that the annual amortization expense for intangible assets held at December 31, 2008 for each of the five years through 2013 is as follows (amounts in thousands):

	Years Ending December 31,				
	2009	2010	2011	2012	2013
Cost of goods sold:					
Intellectual property	$ 4,219	$ 4,148	$ 4,083	$ 4,070	$ 4,016
General and administrative:					
Non-compete and favorable lease agreements	412	236			
Total	$ 4,631	$ 4,384	$ 4,083	$ 4,070	$ 4,016

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10. OTHER ACCRUED LIABILITIES:

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

	December 31,	
	2008	2007
Income taxes payable	$ 2,197	$ 2,414
Accrued medicaid and other rebates	2,726	4,065
Accrued market withdrawal costs	3,598	3,300
Allowance for product returns	3,070	1,875
Other accrued liabilities	5,669	3,616
Total other accrued liabilities	$ 17,260	$ 15,270

11. OPERATING AND CAPITAL LEASES:

Noven has various operating and capital leases related to its computers and equipment. Noven also leases office space in Miami, Florida and New York, New York 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 may be needed in the future, 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. Noven pays a base rent as well as a monthly management fee equal to 1.5% of the base rent. The base rent is subject to annual increases of 3% during the initial 10-year lease term. After the initial term, the rent will be 95% of the fair market rate of the leased space as determined under the Lease. Noven improved the leased space in order to prepare it for its intended use during 2005. The landlord was responsible for up to approximately $0.9 million of leasehold improvements, which were fully paid in 2005. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements 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 $0.5 million for 2008 and $0.4 million for each of 2007 and 2006.

Rent expense under operating leases, including rent expense related to both leases described above, totaled approximately $2.1 million, $1.5 million and $1.2 million for the years ended December 31, 2008, 2007 and 2006, respectively.

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The future minimum rental payments required under noncancelable operating and capital leases as of December 31, 2008 are as follows (amounts in thousands):

	Operating Leases	Capital Leases
2009	$ 1,407	$ 155
2010	1,323	8
2011	971	8
2012	971	8
2013	997	8
Thereafter	891	1
Total lease obligation	$ 6,560	188
Less: portion representing interest		(16)
Capital lease obligation		172
Less: current portion		(145)
Capital lease obligation, net of current portion		$ 27

12. DEFERRED COMPENSATION PLAN:

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

The compensation withheld from Plan participants, together with investment income on the Plan, is reflected as a deferred compensation obligation to participants and is classified as 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 $0.6 million and $0.5 million as of December 31, 2008 and 2007, respectively. The balance of the deferred compensation liability totaled $0.5 million and $0.6 million at December 31, 2008 and 2007, respectively.

13. 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 appreciation rights, stock awards (including restricted common stock), and other permitted awards to selected individuals for up to 6.3 million shares. Prior to January 1, 2006, all

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awards granted to employees under the 1999 Plan were stock options. In 2006, Noven began granting SSARs to employees and nonvested shares of common stock (restricted stock) to non-employee directors in lieu of stock options. The terms and conditions of equity awards (including price, vesting schedule, term and number of shares) 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) stock options cannot be less than the fair market value of the common stock on the date of grant; and (ii) 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, 2008, there were 1.5 million stock options and 2.6 million 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.

Noven granted 70,847 and 26,244 shares of restricted stock to Noven s non-employee directors in June 2008 and May 2007, respectively, as compensation for their service on the Board of Directors. The grants fall under the definition of nonvested shares under SFAS 123(R). The shares vest over each director s one-year service period 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 Issue 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, 2008 and December 31, 2007 there were a total of 92,818 and 48,300 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. 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.

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Stock option and SSAR transactions under the 1999 Plan are summarized as follows (options/SSARs and shares in thousands):

	Stock Options/ SSARs	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at beginning of period	3,511	$ 16.83		
Granted	1,591	10.73		
Exercised	(19)	10.47		
Canceled or expired	(990)	17.30		
Outstanding at end of year	4,093	$ 14.31	4.8	$ 813
Exercisable at end of period	1,816	$ 16.91	2.8	$ 180
Shares of common stock reserved	4,332			

At December 31, 2008, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and nonvested shares, as determined in accordance with SFAS No. 123(R), is approximately $11.1 million before the effect of income taxes. The weighted average period over which this compensation cost is expected to be recognized is 6.2 years. The total fair value of equity grants that vested in each of the years ended December 31, 2008, 2007 and 2006 was $4.4 million, $3.6 million and $3.3 million, respectively. As of December 31, 2008, approximately 3.6 million outstanding options/SSARs are vested or expected to vest. Such options have a weighted average exercise price of $14.60, $0.7 million aggregate intrinsic value and a weighted average remaining life of 4.5 years as of December 31, 2008.

Noven has granted a total of 388,780 shares of restricted stock under the 1999 Plan. The following table summarizes the information regarding Noven s restricted stock as of December 31, 2008 (share amounts in thousands):

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2007	6	$ 22.86
Granted	328	9.90
Vested	(113)	11.57
Nonvested at December 31, 2008	221	$ 9.43

Restricted stock grants in 2008 include an aggregate 257,345 shares of restricted stock granted to two executive officers. In addition, in January 2008, Noven granted a total of 50,000 restricted stock units under the 1999 Plan to Noven s former Chief Executive Officer as part of a separation agreement. The fair value of this award (approximately

$0.7 million) was charged to operations in 2007.

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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.

14. SHARE REPURCHASE PROGRAM:

In 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 treasury as of December 31, 2008 and December 31, 2007. No shares were repurchased under the program in 2008.

15. 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 21. 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

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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 $849,000, $658,000 and $656,000 to the 401(k) Plan for the years ended December 31, 2008, 2007 and 2006, respectively.

16. INCOME TAXES:

The provision (benefit) for income taxes for the years ended December 31, 2008, 2007 and 2006 consists of (amounts in thousands):

	2008	2007	2006
Current income taxes:			
Federal	$ 16,794	$ 24,312	$ 7,123
State	1,153	3,414	1,154
	17,947	27,726	8,277
Deferred income tax (benefit) expense:			
Federal	(6,305)	(51,174)	(241)
State	(213)	(1,427)	(94)
	(6,518)	(52,601)	(335)
Provision (benefit) for income taxes	$ 11,429	$ (24,875)	$ 7,942

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 (amounts in thousands):

	2008	2007
Deferred income tax assets:		
Deferred license revenue	$ 27,574	$ 18,761
Joint venture interest	3,822	3,417
Inventory adjustments and reserves	2,346	3,241
Deferred profit on sales to Novogyne	345	498
Deferred rent credit	211	393
Non-qualified stock options	3,508	2,463
Accrued expenses and sales allowances	4,056	3,416
Basis differences in fixed and intangible assets	32,965	37,064
Other	1,735	964
Valuation allowance	(3,467)	(3,200)
Total deferred income tax assets	73,095	67,017
Deferred income tax liabilities:		
Basis difference in fixed assets	(910)	(1,350)
Net deferred income tax asset	$ 72,185	$ 65,667

At December 31, 2008 and 2007, net deferred tax assets were $72.2 million and $65.7 million, respectively. Realization of these deferred tax assets 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

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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. Noven Therapeutics has historically reported taxable losses in these states and expects to continue to incur state taxable losses in the next few years. These circumstances create negative evidence indicating the need for a valuation allowance at December 31, 2008 and 2007. Noven s valuation allowance for state deferred tax assets was $3.5 million and $3.2 million as of December 31, 2008 and 2007, respectively, due to uncertainty about Noven s ability to realize these state deferred tax assets based on Noven s projection of future state taxable income relating to Noven Therapeutics. If Noven determines, based on future Noven Therapeutics profitability that these state deferred tax assets will more likely than not 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 year ended December 31, 2008, Noven realized $0.3 million of tax benefits arising upon exercise of stock options/SSARs or vesting of restricted stock. In addition, during 2008, Noven charged tax benefit adjustments of $0.3 million against additional paid in capital, which primarily arose from the elimination of deferred tax assets for vested awards which expired unexercised. For the years ended December 31, 2007 and 2006, Noven credited $0.5 million and $3.6 million, respectively, to additional paid-in capital related to the excess tax benefits from the exercise of stock options.

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 (dollar amounts in thousands):

	Years Ended December 31,					
	2008		2007		2006	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$ 11,495	35.0	$ (24,588)	(35.0)	$ 8,375	35.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	360	1.1	(2,336)	(3.3)	690	2.9
Non-taxable interest income	(523)	(1.5)	(1,486)	(2.1)	(1,323)	(5.5)
Non-deductible incentive stock option compensation expense	92	0.3	146	0.2	228	0.9
Research and development expenditures credit	(301)	(0.9)	(167)	(0.2)		
Increase in state tax contingency accruals	16		544	0.7		
Increase in valuation allowance	267	0.8	3,200	4.5		
Cash surrender value of life insurance	(28)	(0.1)	(100)	(0.1)		
Other	51	0.2	(88)	(0.1)	(28)	(0.1)
Income tax (benefit) expense	$ 11,429	34.9	$ (24,875)	(35.4)	$ 7,942	33.2

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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. 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 were 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 income tax rate due to a federal benefit of approximately $0.5 million. As of December 31, 2008, the gross amount of unrecognized tax benefits was approximately $1.3 million. If the $1.3 million is ultimately recognized, approximately $0.9 million would impact the effective income tax rate due to a federal benefit of approximately $0.4 million. Interest and penalties related to income taxes are classified as a component of income tax expense. Approximately $0.5 million were accrued for interest and penalties as of December 31, 2008 and December 31, 2007. Noven does not expect the gross amount of unrecognized tax benefits to significantly increase or decrease within 12 months after December 31, 2008. All of Noven s unrecognized tax benefits pertain to state tax positions.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (amounts in thousands):

	2008	2007
Balance, beginning of year	$ 1,371	$ 909
Additions for tax positions related to the current year	168	324
Additions for tax positions of prior years	162	138
Reductions for tax positions of prior years	(153)	
Reductions due to lapse of statute of limitations	(205)	
Balance, end of year	$ 1,343	$ 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. 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 returns for years 2004 through 2007 remain open and subject to examination by the IRS. During the third quarter of 2008, the IRS initiated an examination of Noven s federal income tax returns for the years ended December 31, 2006 and 2007. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes. Noven s filings with those states remain open for audit for the years 2004 through 2007. In January 2009, the State of New Jersey Division of Taxation initiated an examination of Noven s tax returns for 2004 through 2007. Noven does not expect the outcome of the examinations to materially impact its tax liabilities. Other than the IRS and New Jersey examinations described above, as well as routine state tax inquiries, Noven has not been notified of any other examinations currently taking place related to 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, and the results of which can materially change the amount of unrecognized income tax benefits for tax positions taken, which may increase Noven s income tax liabilities or decrease the amount of deferred tax assets.

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17. SEGMENT AND CUSTOMER DATA:

Noven operates in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, Noven s women s health joint venture with Novartis in which Noven owns a 49% equity interest and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products. Historically, Novogyne was viewed as a component of the Noven Transdermals unit because the joint venture s primary activity involves the marketing and sale in the United States and Canada of patches manufactured by Noven Transdermals. In the fourth quarter of 2008, as a result of management and organizational changes throughout 2008, Noven revised its presentation of reportable segments to reflect the joint venture as a reportable unit distinct from the manufacturing and licensing activities of Noven Transdermals. This view is consistent with the manner in which information is reported for management decision making.

Noven evaluates segment performance for Noven Transdermals and Noven Therapeutics based on segment profit (loss) which consists of segment net revenues less cost of products sold and selling and marketing expenses. Noven evaluates segment performance for Novogyne based on Noven s equity in earnings of Novogyne.

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The table below presents segment information for the periods identified and reconciles segment profit (loss) to the applicable consolidated amounts. Segment disclosures for 2007 and 2006 have been revised to conform to the current presentation. Noven Transdermals net revenues include product revenues from sales to Novogyne of $29.7 million, $29.9 million and $26.6 million for 2008, 2007 and 2006, respectively. 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. There are no other inter-segment revenues. The Noven Therapeutics segment was acquired on August 14, 2007. Consequently, Noven s results of operations include the results of the Noven Therapeutics segment beginning on the Closing Date. Comparative data is provided for 2006 for Noven Transdermals and Novogyne (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Net revenues:			
Noven Transdermals			
Product revenues	$ 53,153	$ 56,223	$ 48,326
License and contract revenues	30,548	17,725	12,363
	83,701	73,948	60,689
Noven Therapeutics			
Product revenues	$ 24,474	$ 9,213	$
Net revenues	$ 108,175	$ 83,161	$ 60,689
Segment profit (loss):			
Noven Transdermals	$ 39,184	$ 35,018	$ 23,214
Noven Therapeutics	(6,169)	(2,034)	
Equity in earnings of Novogyne	45,642	35,850	28,632
Total segment profit	$ 78,657	$ 68,834	$ 51,846
Reconciliation of segment profit to income (loss) before income taxes:			
Segment profit	$ 78,657	$ 68,834	$ 51,846
Research and development	(15,527)	(13,978)	(11,454)
Acquired in-process research and development		(100,150)	
General and administrative	(36,796)	(30,411)	(20,734)
Reversal of contingent milestone liability	5,000		
Interest and other income, net	2,022	5,454	4,272
Loss on auction rate securities	(515)		
Income (loss) before income taxes	$ 32,841	$ (70,251)	$ 23,930

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

	Years Ended December 31,		
	2008	2007	2006
Noven Transdermals	$ 3,584	$ 3,779	$ 3,686
Noven Therapeutics	4,332	1,759	
Not allocated to segments	1,161	1,142	858
Total	$ 9,077	$ 6,680	$ 4,544

Capital expenditures by segment for each year were as follows (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Noven Transdermals	$ 2,645	$ 2,584	$ 5,269
Noven Therapeutics	244		
Not allocated to segments	931	169	992
Total	$ 3,820	$ 2,753	$ 6,261

Segment assets consisted of the following as of December 31, 2008 and 2007 (amounts in thousands):

	December 31, 2008	December 31, 2007
Noven Transdermals	$ 56,362	$ 57,312
Noven Therapeutics	55,902	57,893
Novogyne	24,319	24,310
Assets not allocated to segments[1]	164,983	147,183
Total assets	$ 301,566	$ 286,698

[1] Assets not allocated to segments consist primarily of cash and cash equivalents, investments in auction rate securities and deferred income taxes.

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

	Years Ended December 31,		
	2008	2007	2006
United States	$ 92,197	$ 66,864	$ 43,628
Other countries	15,978	16,297	17,061
Net revenues	$ 108,175	$ 83,161	$ 60,689

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The following table presents information about Noven s revenues by type of product (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Noven Transdermals			
Product revenues:			
Hormone therapy	$ 42,326	$ 42,843	$ 39,784
ADHD	10,827	13,380	8,542
	53,153	56,223	48,326
License and contract revenues	30,548	17,725	12,363
	83,701	73,948	60,689
Noven Therapeutics			
Psychiatry products	$ 24,474	$ 9,213	$
Net revenues	$ 108,175	$ 83,161	$ 60,689

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

	Years Ended December 31,		
	2008	2007	2006
Novogyne	$ 29,719	$ 29,883	$ 26,559
Shire	36,861	27,392	14,556
Novartis Pharma/Novartis	14,518	15,070	15,287
Cardinal	10,390	4,045	
Other	16,687	6,771	4,287
Net revenues	$ 108,175	$ 83,161	$ 60,689

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18. UNAUDITED QUARTERLY CONDENSED FINANCIAL DATA:

(amounts in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Year ended December 31, 2008[1]					
Net revenues	$ 21,482	$ 24,603	$ 25,705	$ 36,385	$ 108,175
Gross profit (product revenues less cost of products sold)	4,887	6,760	4,407	9,712	25,766
(Loss) income from operations	(4,991)	(5,715)	(6,736)	3,134	(14,308)
Equity in earnings of Novogyne[3]	8,267	12,429	13,849	11,097	45,642
Net income	$ 2,592	$ 4,510	$ 5,204	$ 9,106	$ 21,412
Basic earnings per share[4]	$ 0.11	$ 0.18	$ 0.21	$ 0.37	$ 0.87
Diluted earnings per share[4]	$ 0.11	$ 0.18	$ 0.21	$ 0.37	$ 0.87
Year ended December 31, 2007[2]					
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[3]	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[4]	$ 0.20	$ 0.31	$ (2.38)	$ 0.04	$ (1.84)
Diluted earnings (loss) per share[4]	$ 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[3]	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[4]	$ 0.02	$ 0.14	$ 0.21	$ 0.30	$ 0.67
Diluted earnings per share[4]	$ 0.02	$ 0.14	$ 0.20	$ 0.29	$ 0.66

See notes on following page.

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[1] Noven s results for 2008 included: (i) the recognition of $7.2 million of previously deferred license and contract revenues as a result of the termination of our agreements with Shire for the development of an amphetamine patch; (ii) the recognition of $5.0 million in operating income from reversal of an accrued liability related to a future Pexeva® contingent sales milestone; (iii) $3.7 million of charges associated with the voluntary market withdrawal of a portion of the Daytrana® product by Shire; (iv) a $3.8 million charge related to previously manufactured Daytrana® product at risk of exceeding the product s peel force specification during its shelf

life; and (v) a $1.8 million charge related to a patent infringement case.

[2] Noven s results for 2007 included: (i) a $100.2 million charge recorded in the 2007 third quarter for the Noven Therapeutics acquisition purchase price allocated to in-process research and development; (ii) a $3.3 million charge associated with the voluntary withdrawal of a portion of Daytrana® product by Shire; (iii) a $3.3 million fourth quarter charge related to separation arrangements with certain executive officers; and (iv) results of operations of Noven Therapeutics from the date of acquisition (August 14, 2007) through December 31, 2007.

[3] Equity in earnings of Novogyne is typically lower in the first quarter of each year due to Novartis preferred return of $6.1 million, which must be distributed before any allocation of income to Noven.

[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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19. 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 clinical study aimed at determining whether estrogen therapy (ET) use, by women aged 42 to 58, reduces the risk of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. While Noven s HT products are not being used in the study, the market for Noven s 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 Noven manufactures and supplies Daytrana® to Shire at a fixed price. In 2008 and 2007, Noven s net product sales of Daytrana® to Shire were $10.8 million and $13.4 million, respectively. 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, Noven s financial results 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

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expect any activity in this case in the near future, as the court has entered an order to stay proceedings in all its pending and future HT cases except for cases where Wyeth Pharmaceuticals and its affiliates and Pfizer Inc. are the defendants.

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

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

In July 2008, one additional complaint was filed in the United States District Court, District of Minnesota against Wyeth Inc. and other named pharmaceutical companies, including Noven, Novogyne and Novartis. The complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle-Dot®. The plaintiffs claim compensatory and other damages in an unspecified amount.

Each of the aforementioned federal court cases has been, or is expected to be, transferred to the federal multi-district litigation proceedings that are pending in the United States District Court, Eastern District of Arkansas.

Novartis has advised Noven that Novartis is currently named as a defendant in at least 28 additional lawsuits that include approximately 29 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 five lawsuits specifically 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, 2008 was $10.0 million. Novogyne has established reserves in the amount of $9.0 million with an offsetting insurance recovery of $6.7 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, 2008.

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 Noven s manufacture and sale of Daytrana®. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. In July 2007, Johnson-Matthey added Shire as a defendant in this lawsuit. The parties have commenced formal discovery and the case has been scheduled for trial in late 2009.

As of December 31, 2008 and 2007, Noven had reserved $ 2.0 million and $ 0.6 million, respectively, for the matters described above. Noven intends to vigorously defend all of the foregoing lawsuits, but the outcome of these lawsuits cannot ultimately be predicted.

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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 consolidated financial condition, results of operations or cash flows.

FDA WARNING LETTER:

Daytrana® is Noven s transdermal methylphenidate system for the treatment of ADHD, which Noven has licensed globally to Shire. Noven and Shire have received reports from some consumers concerning the difficulty of removing the release liner from certain Daytrana® patches. In the first quarter of 2007, Noven, together with Shire, implemented enhancements to the Daytrana® release liner. While the enhanced release liner has reduced the level of consumer reports, some patients and caregivers continue to have difficulty in removing the release liner from some Daytrana® patches.

In July 2007, Noven received a list of observations from the FDA on Form 483 following an on-site inspection of its 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, Noven submitted to the FDA its response to the Form 483.

In the third quarter of 2007, Shire initiated two voluntary recalls 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. Noven paid Shire $3.3 million in February 2008 related to those recalls. This payment was charged to operations in 2007.

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 the warning letter, which is posted at the FDA s website, the FDA cited Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana ® release liner; and (ii) data supporting the peel force characteristics of Daytrana ® enhanced release liner throughout the product s shelf life. Noven submitted its response to the warning letter on January 30, 2008, which remains under review by the FDA.

In April 2008, a Noven stability protocol identified certain Daytrana® lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana® that did not meet the product s release liner removal specification. In August 2008, Shire initiated the voluntary recall of two additional lots of Daytrana® that did not meet the product s release liner removal specification. Noven paid Shire $3.7 million related to its June and August 2008 recalls, of which approximately $3.1 million has been charged to general and administrative expenses, $0.4 million was recorded as a reduction in revenues and $0.2 million was charged to cost of products sold in 2008. For each of the recalls described above, the amounts reflected as reductions of revenue represent the amounts recognized for product which is expected to be returned. The charge to cost of product sold represents the value of AMI included in such product for which Noven is required to reimburse Shire. The amount charged to general and administrative expenses represents amounts Noven is obligated to reimburse Shire for direct costs of the recalls.

In the fourth quarter of 2008, Noven implemented new manufacturing practices and procedures that helped improve efficiencies associated with existing Daytrana® production.

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Product that fails to meet this test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in the destroyed product. In 2008, Daytrana® cost of products sold exceeded Noven s Daytrana® net revenues by $7.0 million, including $2.6 million of the 2008 Daytrana® Charges. Although Noven has implemented the new manufacturing processes described above, Noven expects the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in destroyed product, unless and until the peel force issue is resolved.

In accordance with SFAS No. 5, Noven has determined that certain previously-manufactured lots that would not have met the new release testing standard are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life. Consequently, during 2008, Noven established a reserve of $3.8 million related to these affected lots. This reserve includes $1.7 million of estimated recall costs that Noven will be required to reimburse to Shire if there are withdrawals or recalls. Of the $3.8 million reserve, approximately $1.7 million has been charged to general and administrative expenses, $1.2 million was recorded as a reduction in revenues and $0.9 million was charged to cost of products sold (of which $0.7 million relates to the cost of AMI). Noven expects that there will be an additional voluntary withdrawal/recall of some Daytrana® lots due to the peel force issue. While Noven believes the $3.8 million reserve is adequate for the costs of such withdrawal/recall, Noven cannot assure that its costs related to this issue will not exceed the amount reserved. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, Noven cannot assure that its testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

In January 2009, Noven received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve. Failure to adequately address the issues raised by the FDA in the warning letter as well as the production and other issues involving Daytrana® could result in additional regulatory action, including fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any such regulatory action would be expected to have a material adverse effect on Noven, including 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:

As of December 31, 2007, Noven was responsible for up to $23.5 million of payments to third parties primarily consisting of milestones related to development, FDA submission, FDA approval and commercial sales of current and developmental products. Of this amount, $11.5 million was accrued as of December 31, 2007. As discussed in Note 7 Contract and License Agreements Synthon Pharmaceuticals Collaboration, during 2007 and 2008 Noven became obligated to make $6.5 million of milestone payments ($3.25 million for each year) to Synthon based on net sales of Pexeva®. During the third quarter of 2008, Noven determined that a $5.0 million contingent

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sales milestone based on net sales of Pexeva® was no longer probable of being achieved and, accordingly, reversed the liability. However, as of December 31, 2008, Noven remains contingently liable for the $5.0 million payment if annual net sales of a future product utilizing the same compound as is used in Pexeva® achieves sales of $30.0 million or more through 2017.

During 2008, Noven became obligated to make a $1.5 million payment to Banner upon FDA approval of Stavzor®. In addition, during 2008, Noven terminated development agreements for certain products which resulted in the elimination of $10.5 million of contingent milestones.

EMPLOYMENT AGREEMENT AND BONUS PLAN:

In connection with the appointment of Noven s President and Chief Executive Officer, Noven entered into an employment agreement, dated April 29, 2008 (the Agreement). The initial two-year term of the Agreement expires on April 28, 2010 and will continue for consecutive one-year terms unless it is terminated by either party under certain conditions. The President and Chief Executive Officer s base salary under the Agreement is approximately $0.7 million, subject to increases at the discretion of the Board of Directors. The President and Chief Executive Officer s annual target incentive bonus under Noven s annual incentive plan during the term will be at least 75% of his base salary. In connection with the Agreement, the President and Chief Executive Officer was granted the following equity awards under the 1999 Plan: (i) SSARs with an aggregate fair value of $1.3 million to acquire 311,529 shares of Noven s common stock at an exercise price of $9.10 per share (the market price on the grant date) which vest at a rate of 25% per year on each anniversary of the grant date; and (ii) 250,000 shares of restricted stock. The shares of restricted stock vest as follows: (a) 50,000 shares were immediately vested upon grant; (b) 50,000 shares vest ratably over three years; and (c) 150,000 shares vest in three equal parts upon Noven s achievement of specified performance targets based on Noven s pre-tax income.

Noven has a formula bonus plan that includes company and individual performance goals. Under the plan, a fixed percentage of each eligible employee s base salary is established as a target incentive bonus award for such employee. An employee s non-financial goals are then considered in determining his or her final bonus award. Noven incurred $4.5 million, $3.4 million and $3.1 million of bonus expenses in 2008, 2007, and 2006, respectively, under this plan. In addition, Noven Therapeutics incurred $0.2 million and $0.8 million of performance and retention bonuses, respectively, in 2007. Management s estimate of the bonus accrual is expensed over the year in which it is earned.

CREDIT FACILITY:

In July 2008, Noven entered into an agreement for a $15.0 million credit facility. In connection with the credit facility and in lieu of granting a security interest in Noven s assets, Noven agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of Noven s financial assets. As of December 31, 2008, no borrowings were outstanding under this facility.

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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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 6, 2009

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Balance Sheets
December 31, 2008 and 2007

(dollars in thousands)

	2008	2007
Assets		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation (Note 6)	$ 36,536	$ 30,120
Due from affiliate Novartis Pharmaceuticals Canada	490	827
Finished goods inventory (net of reserves of $5 and $16 as of December 31, 2008 and 2007)	4,341	5,238
Insurance receivable (Note 7)		288
Other current assets	589	521
Total current assets	41,956	36,994
Noncurrent assets		
Insurance receivable (Note 7)	6,663	6,484
Intangible assets (net of amortization of $47,891 and $41,711 as of December 31, 2008 and 2007) (Note 3)	13,904	20,083
Total noncurrent assets	20,567	26,567
Total assets	$ 62,523	$ 63,561
Liabilities and Members Capital		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc. (Note 6)	$ 7,443	$ 10,004
Accrued liabilities	253	170
Product liability reserve (Note 7)	9,034	8,976
Allowance for returns (Note 4)	7,215	6,036
Total current liabilities	23,945	25,186
Commitments and contingencies (Note 7)		
Members capital		
Capital contributions	32,858	32,858
Accumulated earnings	5,720	5,517
Total members capital	38,578	38,375
Total liabilities and members capital	$ 62,523	$ 63,561

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, 2008, 2007 and 2006

(dollars in thousands)

	2008	2007	2006
Net sales			
Third parties	$ 167,372	$ 145,815	$ 128,974
Novartis Pharmaceuticals Canada, Inc.	2,246	2,173	2,969
	169,618	147,988	131,943
Cost of sales			
Sales to third parties	18,274	16,663	15,887
Sales to Novartis Pharmaceuticals Canada, Inc.	931	903	1,238
Noven royalties	8,411	7,458	6,845
Amortization of license/marketing rights	6,179	6,179	6,179
	33,795	31,203	30,149
Gross profit	135,823	116,785	101,794
Operating expenses			
Sales and marketing expenses	33,943	34,977	32,928
Administrative expenses	3,194	3,221	3,494
Product liability (income)/expenses, net of insurance receivable	334	(114)	897
Income from operations	98,352	78,701	64,475
Other income			
Interest income	1,098	1,145	842
Other income	31		
Net income	$ 99,481	$ 79,846	$ 65,317

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, 2008, 2007 and 2006

(dollars in thousands)

	Total
Members capital at January 1, 2006	$ 36,812
Net income	65,317
Distributions to Novartis	(37,050)
Distributions to Noven	(28,580)
Members capital at December 31, 2006	36,499
Net income	79,846
Distributions to Novartis	(43,134)
Distributions to Noven	(34,836)
Members capital at December 31, 2007	38,375
Net income	99,481
Distributions to Novartis	(53,646)
Distributions to Noven	(45,632)
Members capital at December 31, 2008	$ 38,578

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, 2008, 2007 and 2006

(dollars in thousands)

	2008	2007	2006
Cash flows from operating activities			
Net income	$ 99,481	$ 79,846	$ 65,317
Adjustments to reconcile net income to net cash provided by operating activities			
Amortization of license/marketing rights	6,179	6,179	6,179
Obsolescence reserve	(11)	3	(19)
Changes in assets and liabilities			
(Increase) decrease in due from affiliate Novartis Pharmaceuticals Corporation	(6,416)	(6,432)	(5,737)
Decrease (increase) in due from affiliate Novartis Pharmaceuticals Canada, Inc.	337	290	(1,117)
(Increase) decrease in finished goods inventory	908	(1,171)	4
Decrease (increase) in other current assets	(68)	52	(265)
Decrease (increase) in insurance receivable	109	527	(3,788)
Increase (decrease) in due to affiliate Noven Pharmaceuticals, Inc.	(2,561)	1,438	(1,221)
(Decrease) increase in accrued liabilities	83	(207)	(177)
(Decrease) increase in product liability reserve	58	(653)	4,684
(Decrease) increase in allowance for returns	1,179	(1,902)	1,770
Net cash provided by operating activities	99,278	77,970	65,630
Cash flows from financing activities			
Distributions to members (Note 5)	(99,278)	(77,970)	(65,630)
Net cash used in financing activities	(99,278)	(77,970)	(65,630)
Net change in cash			
Cash and cash equivalents			
Beginning of year			
End of year	$	$	$

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2008

(dollars in thousands)

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 as agreed to by the Members, have been recorded by the Company at Novartis carryover basis of zero. Noven contributed $7,500 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 were no sales of this product in 2008.

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
December 31, 2008

(dollars in thousands)

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, 2008, 2007, and 2006 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. All inventory represents finished goods purchased directly from Noven.

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 and other current market trends. 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
December 31, 2008

(dollars in thousands)

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,		
	2008	**2007**	**2006**
Gross sales	$ 195,748	$ 169,174	$ 151,932
Sales returns	$ 4,645	$ 1,447	$ 5,732
Managed health care rebates	14,578	13,226	10,117
Cash discounts	3,920	3,387	3,042
Medicaid and Medicare Part D rebates including prescription drug savings cards	1,340	1,637	981
Chargebacks	1,423	1,298	1,032
Other discounts	2,470	2,364	2,054
Total sales allowances	28,376	23,359	22,958
Net sales to third parties	$ 167,372	$ 145,815	$ 128,974

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 $164, $144, and $126 for 2008, 2007, and 2006, 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
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December 31, 2008

(dollars in thousands)

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, 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 paid by Noven to sanofi-aventis, and by the Company to Noven, was $40,000. The Company also incurred and capitalized $272 of legal services related to the acquisition.

The Company allocated $3,477 to the value of the inventory and the remaining $61,795 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 $47,891 and $41,711 as of December 31, 2008 and 2007. Amortization expense is $6,179 per year and is included in Cost of Sales.

Based on 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, 2008 and 2007. Further evaluations may be required if additional declines in the market for CombiPatch® develop due to the HT studies (Note 7) 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 were no sales of the product in 2008.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2008

(dollars in thousands)

The activity for the allowances for returns for the years ended December 31, 2008 and 2007 is as follows:

Balance January 1, 2006	$ 6,168
Current year provision	4,342
Prior year adjustment	1,390
Deduction returns processed	(3,962)
Balance December 31, 2006	7,938
Current year provision	3,372
Prior year adjustment	(1,925)
Deduction returns processed	(3,349)
Balance December 31, 2007	6,036
Current year provision	3,982
Prior year adjustment	663
Deduction returns processed	(3,466)
Balance December 31, 2008	$ 7,215

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 $1,000, admitting a new member, acquiring or disposing of assets with a value in excess of $500 or settlement of litigation in excess of $1,000. 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 annually, for the current and all prior fiscal years.

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Vivelle Ventures LLC
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Notes to Financial Statements
December 31, 2008

(dollars in thousands)

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 multiplied by a fraction, the numerator of which is the aggregate net income from sales of Vivelle® and the denominator of which is the aggregate net sales of Vivelle® in that period.

Third, any remaining net income attributable to sales of Vivelle® for each fiscal year is to be allocated 60% to Novartis and 40% to Noven until the cumulative amount of such net income equals the product of $10,000 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 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.

The distributions (includes estimated tax payments) and estimated tax payments made to Novartis and Noven are as follows:

	Distributions Years Ended December 31,			Estimated Tax Payments Years Ended December 31,		
	2008	2007	2006	2008	2007	2006
Novartis	$53,646	$43,134	$37,050	$	$3,534	$2,971
Noven	45,632	34,836	28,580	3,600	5,992	2,212

There were no estimated tax payments made for Novartis in 2008 because the Company is not required to make estimated tax payments on behalf of New Jersey resident partners.

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Vivelle Ventures LLC
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Notes to Financial Statements
December 31, 2008

(dollars in thousands)

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 $6,100 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 2008 that would trigger a dissolution of the Company.

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.

Management and defense of 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, 2008, 2007 and 2006, Novartis charged the Company $3,232, $3,173 and $2,989, respectively, for these services.

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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 $36,536 and $30,120, as of December 31, 2008 and 2007, 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, 2008, 2007 and 2006 at an average annual rate of 3.50%, 5.48% and 5.25%, respectively. During these periods, interest of $1,098, $1,145 and $842, respectively, was earned and is reflected in the amount Due from affiliate Novartis Pharmaceuticals Corporation.

The Members have agreed that Novartis is responsible for managing the receivables balances and Novartis bears the risk of the balances not being recovered in full. However, the Company records 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,	
	2008	**2007**
Balance at the beginning of the period	$ 30,120	$ 23,689
Net sales third parties (excluding returns)	172,018	147,261
Sales returns processed	(3,466)	(3,349)
Interest income on amounts due from Novartis	1,098	1,145
Distributions by Novartis to members	(99,278)	(77,970)
Payments made by Novartis to Noven for marketing services, inventory purchases and royalties	(61,272)	(57,771)
Disbursements made by Novartis on behalf of the Company	(2,035)	(2,175)
Novartis service charges	(3,232)	(3,173)
Cash received from Novartis Pharmaceuticals Canada	2,583	2,463
Total	$ 36,536	$ 30,120

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.

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

During the years ended December 31, 2008, 2007 and 2006, Noven charged the Company $23,234, $21,771, and $20,926, 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, 2008, 2007 and 2006 were $8,750, $11,251, and $10,551, 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.

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 $8,411, $7,458 and $6,845 for the years ended December 31, 2008, 2007 and 2006, respectively.

Inventory Purchases

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, 2008, 2007 and 2006, the Company purchased products from Noven in the amounts of $18,278, $18,575 and $17,013, 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.

In January 2009, Noven received from the FDA a list of observations on Form 483 following an on-site inspection of its manufacturing facilities. Like the warning letter, the majority of the observations relate to the manufacture of a product unrelated to the Company. Failure to adequately address the issues raised by the FDA in the warning letter as well as the production issues could result in additional regulatory action, including 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.

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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, 2008	2007
Purchases of inventory	$ 2,577	$ 4,600
Services provided by Noven	3,239	3,710
Royalties	1,627	1,694
	$ 7,443	$ 10,004

7. Commitments and Contingencies

Litigation, Claims and Assessments

As of December 31, 2008, there have been 57 lawsuits that include 71 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 57 lawsuits filed, 22 lawsuits have been dismissed and 1 lawsuit has been settled for a nominal amount. For the remaining 34 pending lawsuits, 5 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 2 name only the Company. The remainder of the 26 lawsuits only name Novartis.

The Company s operating agreements contain a number of indemnification provisions in which the joint venture has indemnified the members relating to product liability losses. Novartis and Noven 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 $9,034 and $8,976 as of December 31, 2008 and 2007, 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 $6,663 and $6,772 as of December 31, 2008 and 2007, 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.

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The Company plans to pursue having these claims treated as a serial loss for insurance purposes. As of December 31, 2008, 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.

For the year ended December 31, 2004 the Company had a claims-made insurance policy with a $50 deductible per claim and a $10,000 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 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 January 30, 2008, the Company had a claims-made insurance policy with a $150 deductible per claim and a $5,000 aggregate limit, including defense costs. For the period January 31, 2008 through December 31, 2008, the Company had a claims-made insurance policy with a $200 deductible per claim and a $5,000 aggregate limit, including defense costs. These policies contain 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. Claims made subsequent to 2004 for exposure prior to the label change are covered under the tail coverage obtained in 2004.

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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. As widely reported, financial markets in the United States have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. The Company has currently recorded a product liability insurance receivable in the amount of $6,663 due from a subsidiary of American International Group (AIG). Although AIG has advised that its commercial insurance subsidiaries remain well-capitalized despite the parent company s recent liquidity issues and diminished financial position, we cannot assure that the insurance carrier will pay the amounts that the Company believes are owed under the policy, either due to a change in the carrier s financial condition, a coverage dispute or otherwise.

Enacted State Laws

The Company is subject to a variety of 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.

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.

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HT Studies

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

Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage, including a new five-year study aimed at determining whether ET used by women aged 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. As discussed in Note 3, 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.

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 38%, 38% and 19% in 2008, 36%, 39% and 20% in 2007 and 38%, 37% and 20% in 2006.

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Noven Pharmaceuticals, Inc. and Subsidiaries
Schedule II Valuation and Qualifying Accounts
For the years ended December 31, 2008, 2007 and 2006

(Amounts in thousands)	Balance, beginning of year	Additions Charged to costs and expenses	Additions Charged to other accounts	Deductions	Balance, end of year
2008					
Allowance for doubtful accounts	$ 53	$ 19	$ 200 [1]	$	$ 272
Allowance for cash discounts and chargebacks	199	2,149		(2,111)	237
Allowance for rebates	4,065	7,285		(8,624)	2,726
Allowance for returns	1,875	3,410	(200) [1]	(2,015)	3,070
Allowance for product recalls	3,300	7,456	(208) [2]	(6,950)	3,598
Valuation allowance for deferred tax assets	3,200	267			3,467
2007					
Allowance for doubtful accounts	$ 67	$ (14)	$	$	$ 53
Allowance for cash discounts and chargebacks		628	376 [3]	(805)	199
Allowance for rebates		3,289	3,792 [3]	(3,016)	4,065
Allowance for returns		666	1,578 [3]	(369)	1,875
Allowance for product recalls		3,300			3,300
Valuation allowance for deferred tax assets		3,200			3,200
2006					
Allowance for doubtful accounts	$ 53	$ 17	$	$ (3)	$ 67

[1] Represents credits expected to be issued against customer receivable balances related to product returns.

[2] Represents amount of inventory

reserve related to the voluntary market withdrawal of Daytrana® product.

3 Liabilities assumed in connection with the acquisition of Noven Therapeutics (f/k/a JDS Pharmaceuticals LLC) on August 14, 2007.