ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 29, 2002

# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 10-K

**FOR ANNUAL AND TRANSITION REPORTS**

**PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**(Mark One)**

**x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

**For the fiscal year ended December 31, 2001**

**or**

**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: 39040**

# ENDO PHARMACEUTICALS HOLDINGS INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **13-4022871** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**100 Painters Drive**
**Chadds Ford, Pennsylvania 19317**
**(Address of Principal Executive Offices)**

**(Registrant s Telephone Number, Including Area Code): (610) 558-9800**

**Securities registered pursuant to Section 12(b) of the Act:**

| **Title of Each Class Registered** | **Name of Each Exchange on Which** |
|---|---|
| **Common Stock** | **Nasdaq** |
| **Class A Transferable Warrants to Purchase Common Stock at $.01 per Share in Certain Circumstances** | **Nasdaq** |

**Securities registered pursuant to Section 12(g) of the Act: N/A**

**Annual Report for the Year Ended December 31, 2001**

Indicate by check þ whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check ü 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. o

Aggregate market value, as of March 25, 2002, of Common Stock held by non-affiliates of the registrant: $307,798,000 based on the last reported sale price on the Nasdaq.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of March 25, 2002: 102,063,950.

**Documents Incorporated by Reference**

Portions of the registrant s Information Statement relating to its Annual Meeting are incorporated by reference in Part III of this Report. In addition, the Company s Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended is incorporated by reference into this Report, and the Company s Registration Statement on Form S-3 dated October 17, 2001, are incorporated by reference into this Report.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX TO FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2001**

**Forward Looking Statements**

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales and consolidated EBITDA contained in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Management s Discussion and Analysis of Financial Condition and Results of Operations, Business and elsewhere in this Report could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this Report. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this Report include, among others:

- our ability to successfully develop, commercialize and market new products;
- results of clinical trials on new products;
- competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;
- market acceptance of our future products;
- government regulation of the pharmaceutical industry;
- our dependence on a small number of products;
- our dependence on outside manufacturers for the manufacture of our products;
- our dependence on third parties to supply raw materials and to provide services for the core aspects of our business;
- new regulatory action or lawsuits relating to the use of narcotics in most of our core products;
- our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;
- our ability to protect our proprietary technology;
- our ability to successfully implement our acquisition strategy;
- the availability of controlled substances that constitute the active ingredients of some of our products and products in development;
- the availability of third-party reimbursement for our products; and
- our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future.

**PART I**

**Item 1.** ***Our Business***

**Overview**

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $14 billion for the 12 months ended December 31, 2001. Our primary area of focus is analgesics, which according to IMS Health data was the second most prescribed class of medication in the United States in 2001.

Endo was incorporated on November 18, 1997 under the laws of the state of Delaware and has its principal executive offices at 100 Painters Drive, Chadds Ford, Pennsylvania 19317 (telephone number: (610) 558-9800).

We have a portfolio of branded products that includes established brand names such as Percocet®, Lidoderm®, Percodan® and Zydone®. Branded products comprised approximately 68%, 76% and 67% of net sales for fiscal years 1999, 2000 and 2001, respectively. Through a national dedicated contract sales force of approximately 230 sales representatives, we market our branded pharmaceutical products to doctors, retail pharmacies and other healthcare professionals throughout the United States.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. We enhance our financial flexibility by outsourcing many of our functions, including manufacturing. Currently, our primary suppliers of contract manufacturing services are Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals), Novartis Consumer Health, Inc. and Teikoku Seiyaku Pharmaceuticals.

**Our Strategy**

Our business strategy is to continue to strengthen our position as a market leader in pain management, while opportunistically pursuing other markets, especially those with a complementary therapeutic or physician base. The elements of our strategy include:

*Capitalizing on our established brand names through focused marketing and promotion.* We consider two of our brands, Percocet® and Percodan®, to be gold standards of pain management. Percocet® has been prescribed by physicians since 1971, while Percodan® has been prescribed since 1950. We believe that we have established credibility with physicians as a result of these products history of demonstrated effectiveness and safety. We plan to continue to capitalize on this brand awareness to market new products, as well as new formulations and dosages of our existing branded products. We also believe that our strong corporate and product reputation leads to more rapid adoption of our new products by physicians.

*Developing proprietary products and selected generics.* To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions by treating moderate-to-severe pain. We are also developing new patent protected products that leverage our patent portfolio covering the combination of a number of compounds, including opioids and N-methyl-D-aspartate (NMDA)-receptor antagonists, drugs that may substantially improve the treatment of pain by addressing the underlying processes associated with acute and chronic pain, including those processes relating to increased sensitivity to pain signals and the development of analgesic tolerance. These products include MorphiDex®, a patented combination of morphine and the NMDA-receptor antagonist, dextromethorphan, which is currently in Phase III clinical trials. We anticipate resubmitting an amendment to the existing new drug application (also known as an NDA), with the U.S. Food and Drug Administration (or the FDA), in the late third quarter or during the fourth quarter of 2002. In addition, we are co-developing an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals. This product is currently in Phase III clinical trials along with an immediate-release (IR) form of oxymorphone, and we continue to anticipate filing NDAs for both of these products with the FDA in the second half of 2002.

We have also developed extended-release version of oxycodone, an AB-rated generic version of OxyContin®, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin® generated U.S. sales of approximately $1.5 billion in 2001, up from approximately $1.0 billion in 2000. We have filed and amended an abbreviated new drug application (or ANDA) with the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin®. We believe we are the first company to have filed an ANDA with the FDA for the bioequivalents of the 10mg, 20mg and 40mg strengths of OxyContin®, thereby entitling us to 180 days of marketing exclusivity with respect to these strengths of this product. See Item 3. Legal Proceedings.

*Developing and marketing product line extensions for our existing brands.* We plan to continue to develop and market extensions of existing products through new formulations, dosages and delivery platforms. During the fourth quarter of 1999, we complemented the existing Percocet® 5.0/325 with three new formulations: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650. Additionally, during the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet®10.0/325. Net sales of Percocet® products increased from $92.4 million in 2000 to $101.0 million in 2001. We have also implemented this strategy with a line extension of our Zydone® product, a combination of hydrocodone and acetaminophen.

*Acquiring and in-licensing complementary products, compounds and technologies.* We look to continue to enrich our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. In July 2000, we acquired Algos and the rights to the patented development-stage product MorphiDex®. Through this acquisition, we also acquired rights to a portfolio of patents, including those covering the combination of the NMDA-antagonist, dextromethorphan, with opioids. In November 1998, we in-licensed Lidoderm®, which became the first FDA-approved product for the relief of the pain of post-herpetic neuralgia, a chronic, painful condition that may follow an attack of shingles. We launched this product in September 1999. Net sales of Lidoderm® increased from $22.5 million in 2000 to $40.9 million in 2001. In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals under which we are co-developing an oral extended-release version of oxymorphone. We also entered into a collaboration agreement with Lavipharm Laboratories Inc., under which we obtained rights to certain of Lavipharm s existing drug-delivery platforms in combination with defined drug substances.

**Our Competitive Strengths**

We believe that we have established a position as a market leader among pain-focused pharmaceutical companies by capitalizing on our following core strengths:

*Established portfolio of branded products.* We have assembled a core portfolio of branded pharmaceutical products to treat and manage pain. These products include Percocet® and Percodan®, which have been marketed since 1971 and 1950, respectively, and which we consider to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness. According to IMS Health data, approximately 86% of oxycodone with acetaminophen prescriptions are written as Percocet. We believe our close relationships with physicians who we consider to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to improve our penetration in these types of institutions. We believe this interaction has also allowed us to pursue, through in-licensing, products targeted at additional or novel indications, such as Lidoderm® for post-herpetic neuralgia.

*Substantial pipeline focused on pain management.* As a result of our focused research and development effort, we have three products in Phase III and three products in Phase II clinical trials. If clinical studies progress as we anticipate, we expect to file NDAs with the FDA in 2002 for our three products currently in Phase III clinical trials. These are MorphiDex®, oxymorphone ER and oxymorphone IR.

*Research and development expertise.* Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with narcotic analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with opioids and complex formulations. We believe this expertise allows for timely FDA

approval of our products. We have demonstrated our ability to commercialize our research and development efforts during the last four years through the launch of a number of new products and product extensions all of which, in the aggregate, contributed approximately 54% of our net sales in 2001.

*Selective focus on generic products.* Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed this strategy successfully with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent of MS Contin®, a Purdue Frederick product. In addition, we believe we are the first company to have filed an ANDA with the FDA for the bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. We believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. See Governmental Regulation.

*Targeted national sales and marketing infrastructure.* We market our products directly to physicians through a dedicated contract sales force of approximately 160 community-based field representatives and 70 specialty/ institutional representatives. The sales force focuses on high-prescribing physicians in pain management, surgery, oncology and primary care. These sales representatives, as well as regional and district managers, are provided exclusively to us pursuant to an agreement with Ventiv Health U.S. Sales Inc. We have a flexible arrangement with Ventiv, whereby we have the option to hire all of these sales representatives and managers as our full time employees at any time. We maintain an internal sales management infrastructure to direct and focus these sales force efforts.

*Experienced and dedicated management team.* With an average of approximately 20 years of experience in the pharmaceutical industry, our management team has a proven track record of building our business through internal growth as well as acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997. In September 1999, management in-licensed and launched Lidoderm®, an orphan drug for the treatment of the pain of post-herpetic neuralgia. In July 2000, we acquired Algos to obtain its patent-protected platform and technology. Management has received FDA approval on more than fifteen new products and product extensions since 1997 and has grown net sales from approximately $108.4 million in 1998 to approximately $252.0 million in 2001. In addition, management has vested stock options to acquire up to 11% of our common stock and has the potential to receive as much as an additional 9% of our common stock through options that vest if the price of our common stock reaches specified defined targets. These options are exercisable solely for shares currently held by Endo Pharma LLC, and their exercise will not dilute the ownership of our other common stockholders.

**Our Industry**

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $14.3 billion for the 12 months ended December 31, 2001. This represents an approximately 28% compounded annual growth rate since 1998. Our primary area of focus within this market is analgesics. In 2001, analgesics were the second most prescribed medication in the United States with over 232 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 76% of the analgesics prescriptions in 2001. This market segment has grown to $3.6 billion for the 12 months ended December 31, 2001, representing a compound annual growth rate of 31% since 1998. If branded products were substituted for generic products, we believe

the dollar value of this market segment would be substantially larger. The growth in this segment has been primarily fueled by the:

increasing physician recognition of the need and patient demand for effective treatment of pain;

aging population (according to the U.S. Census Bureau, in 1990 the population aged 65 and older reached 31 million people and is expected to grow to 40 million people by 2010, representing 29% growth over this period);

introduction of new and reformulated branded products; and

increasing number of surgical procedures.

**Product Overview**

The following table summarizes select pain products in our portfolio as well as those in development:

| Product | Active ingredient | Branding | Status |
|---|---|---|---|
| Percocet® | oxycodone and acetaminophen | Branded | Marketed |
| Lidoderm® | lidocaine 5% | Branded | Marketed |
| Percodan® | oxycodone and aspirin | Branded | Marketed |
| Zydone® | hydrocodone and acetaminophen | Branded | Marketed |
| Morphine Sulfate ER | morphine sulfate | Generic | Marketed |
| MorphiDex® | morphine and dextromethorphan | Branded | Phase III |
| Oxymorphone ER | oxymorphone hydrochloride | Branded | Phase III |
| Oxymorphone IR | oxymorphone hydrochloride | Branded | Phase III |
| HydrocoDex | hydrocodone, acetaminophen, and dextromethorphan | Branded | Phase II |
| OxycoDex | oxycodone and dextromethorphan | Branded | Phase II |
| PercoDex | oxycodone, acetaminophen and dextromethorphan | Branded | Phase II |
| Oxycodone ER | oxycodone | Generic | ANDA filed; subject to litigation(1) |

(1) See Item 3. Legal Proceedings.

*Branded Products*

*Percocet*®. We consider Percocet® to be a gold standard of pain management. Launched in 1971, Percocet® is approved for the treatment of moderate-to-severe pain. Although Percocet® has faced generic competition for more than 15 years, in 2001, according to the IMS National Prescription Audit, approximately 12.5 million prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet®, of which, due to generic substitution, only approximately 14% were filled by pharmacists with our brand Percocet®.

During the fourth quarter of 1999, we introduced three new strengths of Percocet®: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650, complementing the existing Percocet® 5.0/325. Prior to the launch of these products, physician prescribing practices had indicated that over 80% of prescriptions were written for amounts other than the label amount. As an example, the current prescription information for the original Percocet®, Percocet® 5.0/325, calls for one tablet every six hours. Approximately 30% of prescriptions written directed patients to take two tablets every four hours, translating into a dosage of 10mg every four hours. By offering new prescription strengths, we have enabled physicians to prescribe one tablet of the proper dose for their patients, facilitating greater ease and compliance. On January 3, 2000, the Food and Drug Administration approved another manufacturer s ANDA for a generic equivalent to Percocet® 7.5/500 and

Percocet® 10.0/650. This generic equivalent became available in April 2001. During the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325. These new dosage forms allow physicians the flexibility of increasing the dose of narcotic while still maintaining a low level of acetaminophen. There is currently no generic equivalent available for these new dosage forms. All of the Percocet® products were responsible for net sales of $51.5 million, $92.4 million and $101.0 million in the years 1999, 2000 and 2001, respectively. The Percocet® franchise accounted for approximately 40% of our 2001 net sales.

*Lidoderm*®. Lidoderm® was launched in September 1999. A patented, topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain from post-herpetic neuralgia. There are approximately 200,000 patients per year who suffer from this condition in the United States, the majority of whom are elderly. The FDA has granted Lidoderm® orphan status, meaning that no other lidocaine-containing patch product can be approved for this indication until March 2006. In 1999, 2000 and 2001, Lidoderm® net sales were $5.7 million, $22.5 million and $40.9 million, respectively. Lidoderm® accounted for approximately 16% of our 2001 net sales.

*Percodan*®. Launched in 1950 for the treatment of moderate-to-severe pain, we also consider Percodan® to be a gold standard of pain management. In 2001, according to the IMS National Prescription Audit, approximately 398,000 prescriptions for oxycodone hydrochloride and oxycodone terephthalate in combination with aspirin were written for the brand name Percodan®. Due to generic substitution, only approximately 21% of these prescriptions were filled by pharmacists with Percodan®.

*Zydone*®. In February 1999, we launched Zydone® tablets, branded hydrocodone/acetaminophen products for the relief of moderate-to-severe pain. Zydone® is available in three strengths, 5.0mg, 7.5mg and 10.0mg, each in combination with 400mg acetaminophen.

*Other.* The balance of our branded portfolio consists of a number of products, none of which accounted for more than 5% of our total net sales in the 2001 fiscal year.

**Generic Products**

When a branded pharmaceutical product is no longer protected by the relevant patents, normally as a result of a patent s expiration, third parties have an opportunity to introduce generic counterparts to such branded product. Generic pharmaceutical products are therapeutically equivalent to their brand-name counterparts and are generally sold at prices significantly less than the branded product. Accordingly, generic pharmaceuticals may provide a safe, effective and cost-effective alternative to users of branded products.

Our generic portfolio is currently comprised of products that cover a broad range of indications, most of which are focused in pain management. Our primary generic product is morphine sulfate extended-release tablets, which accounted for 17% of our total net sales in 2001. Launched in November 1998, morphine sulphate extended-release tablets are a bioequivalent of MS Contin®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength, thereby completing the product line. We also have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 9% of our total net sales in 2001. The balance of our generic portfolio consisted of several products, none of which accounted for more than 5% of our total net sales for 2001.

We principally pursue the development and marketing of generic pharmaceuticals that have one or more barriers to entry. The characteristics of the products that we may target for generic development may include:

complex formulation or development characteristics;

regulatory or legal challenges; or

difficulty in raw material sourcing.

We believe products with these characteristics will face a lesser degree of competition, and, therefore provide longer product life cycles and/or higher profitability than commodity generic products.

**Products in Development**

Our pipeline portfolio contains products intended to address acute pain, chronic pain and neuropathic pain conditions. We cannot predict when or if any of these products will be approved by the FDA.

*MorphiDex*®. We are currently conducting Phase III clinical trials of MorphiDex®, a patented combination of morphine and the NMDA-receptor antagonist, dextromethorphan. A new drug application was submitted to the FDA by Algos for MorphiDex® in August 1998. In August 1999, Algos received a not-approvable letter received from the FDA. A not-approvable letter is issued by the FDA for various reasons and outlines deficiencies that must be corrected prior to a product s approval. Following our acquisition of Algos in July 2000, we met with the FDA in September 2000 to discuss MorphiDex®. At this meeting, the FDA requested, among other things, the submission of a second pivotal chronic multiple dosing study to support the intended indication of MorphiDex®. We have initiated three chronic multiple dosing studies of MorphiDex®. If successful, these studies will complement the already successful pivotal chronic multiple dosing study previously submitted to the FDA and provide the data necessary for the commercial optimization of the product. We intend to file with the FDA an amendment to the existing NDA for MorphiDex® as soon as possible and, subject to the successful completion of these studies, including successful patient recruitment, currently expect to be in a position to file this reapplication in the late third quarter or during the fourth quarter of 2002. Under the guidelines included in the Prescription Drug User Fee Act of 1992, as amended, we anticipate that the FDA will respond within six months after its acceptance of the reapplication. Once approved, we expect MorphiDex® to compete in the $2 billion severe pain market.

*Oxymorphone ER.* We are currently conducting Phase III clinical trials of an oral extended-release version of oxymorphone. We have marketed oxymorphone in the U.S. for over 40 years in injection and suppository form. We are co-developing this oral extended-release version of oxymorphone with Penwest Pharmaceuticals and currently expect to be in a position to file the NDA application in the second half of 2002. Once approved, we expect oxymorphone ER will also compete in the $2 billion severe pain market.

*Other.* In addition to MorphiDex® and our oral extended-release version of oxymorphone, we have a third product in Phase III clinical trials (oxymorphone immediate release (IR)), three in Phase II (HydrocoDex , OxycoDex and PercoDex ) and other products in various stages of development. These analgesic products address the broad spectrum of pain management.

**Competition**

The pharmaceutical industry is highly competitive. Our competitors vary depending upon therapeutic and product categories. Competitors include the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States, including, Abbott Laboratories, Johnson & Johnson, The Purdue Frederick Company, Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc.

We compete principally through our targeted product development strategies. In addition to product development, other competitive factors in the pharmaceutical industry include product quality and price, reputation and access to technical information.

The competitive environment of the branded product business requires us to continually seek out technological innovations and to market our products effectively. However, our branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. The entrance of generic competition to one of our branded products generally reduces our market share and adversely affects our profitability and cash flows.

Newly introduced generic products with limited or no other generic competition are typically sold at higher selling prices. As competition from other generic products increases, selling prices of the generic products typically decline. Consequently, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing relationships.

We have witnessed a consolidation of our customers as chain drug stores and wholesalers merge or consolidate. In addition, a number of our customers have instituted source and bundling programs that enhance the access that suppliers who participate in such source programs have to the customers of the wholesaler. Consequently, there is heightened competition among drug companies for the business of this smaller and more selective customer base of chain drug stores and large wholesalers.

**Research and Development**

We devote significant resources to research and development. At December 31, 2001, our research and development staff consisted of 52 employees, primarily based in Garden City, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. For fiscal years 1999, 2000 and 2001, our expenditures on research and development were $9.4 million, $26.0 million and $39.0 million, respectively. In addition to our internal research and development staff, we have agreements and arrangements with various contract research organizations to conduct and coordinate our toxicology and clinical studies.

**Seasonality**

Although our business is affected by the purchasing patterns and concentration of our customers, our business is not materially impacted by seasonality. Generally, the fourth fiscal quarter has relatively higher net sales than each of the first three fiscal quarters.

**Customers**

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors individually accounted for 27%, 20% and 13% of our net sales in 1999. Three distributors and one pharmacy chain individually accounted for 26%, 16%, 12% and 10%, respectively, of our net sales in 2000. Three distributors and one pharmacy chain individually accounted for 28%, 24%, 19% and 10%, respectively, of our net sales in 2001.

Recently, there have been numerous mergers and acquisitions among wholesale distributors as well as rapid growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased.

**Patents, Trademarks, Licenses and Proprietary Property**

We currently hold 12 U.S. issued patents and three foreign issued patents, approximately 15 U.S. patent applications pending and approximately 50 foreign patent applications pending with respect to our products. We have licenses for 31 U.S. issued patents, one U.S. patent application pending, 66 foreign issued patents and 26 foreign patent applications pending. The effect of these issued patents is that they provide us patent protection for the claims covered by the patents.

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. All of our brand products and certain generic products, such as Endocet® and Endodan®, are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Licenses and Collaboration Agreements. There can be no assurance that any of our patents, licenses or other intellectual property will afford us any protection from competition.

We rely on confidentiality agreements with our employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will not

be breached, that we will have adequate remedies for any breach, or that others will not independently develop equivalent proprietary information or other third parties will not otherwise gain access to our trade secrets and other intellectual property.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property and to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Item 3. Legal Proceedings.

**Governmental Regulation**

The manufacture, testing, packaging, labeling, distribution, sales and marketing of our products and our ongoing product development activities are subject to extensive and rigorous regulation at both the federal and state levels. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations govern or influence the testing, manufacture, safety, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDA and ANDAs, civil sanctions and criminal prosecution.

FDA approval is required before each dosage form of any new drug can be marketed. Applications for FDA approval must contain information relating to efficacy, safety, toxicity, pharmacokinetics, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling, and quality control. The FDA also has the authority to revoke previously granted drug approvals. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations.

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

*NDA Process*

FDA approval is required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The NDA must contain complete pre-clinical and clinical safety and efficacy data or a right of reference to such data sponsored by the applicant. Before dosing a new drug in healthy human subjects or patients may begin, stringent government requirements for preclinical data must be satisfied. The preclinical data, typically obtained from studies in animals, as well as from laboratory studies, are submitted in an Investigational New Drug application, or IND, or its equivalent in countries outside the United States where clinical trials are to be conducted. The preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap.

In Phase I, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, the product is tested for safety, adverse effects, dosage, tolerance absorption, metabolism, excretion and other elements of clinical pharmacology.

Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.

Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk- benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. In some cases, the FDA allows a company to rely on data developed in foreign countries or previously published data, which eliminates the need to independently repeat some or all of the studies.

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditures of substantial resources. Preparing an NDA or marketing authorization application involves considerable data collection, verification, analysis and expense, and there can be no assurance that approval from the FDA or any other health authority will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny an NDA or marketing authorization application if the regulatory criteria are not satisfied, or such authorities may require additional testing or information.

As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data on safety. The post-marketing studies could be used to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products.

*ANDA Process*

FDA approval of an ANDA is required before a generic equivalent of an existing, or listed drug can be marketed. We usually receive approval for such products by submitting an ANDA to the FDA. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and instead relies on bioequivalence studies. Bioequivalence compares the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of the test and reference drugs are the same, the two drugs are bioequivalent and regarded as therapeutically interchangeable.

An ANDA also may be submitted for a drug authorized by approval of an ANDA suitability petition. Such petitions may be submitted to secure authorization to file an ANDA for a product that differs from a previously approved drug in active ingredient, route of administration, dosage form or strength. For example, the FDA has authorized the substitution of acetaminophen for aspirin in certain combination drug products and switching the drug from a capsule to tablet form. Bioequivalence data may be required, if applicable, as in the case of a tablet in place of a capsule, although the two products would not be rated as interchangeable.

The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving, generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

The Generic Drug Enforcement Act of 1992 allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Act requires the FDA to not accept or review ANDAs for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Generic Act allows for civil penalties and withdrawal of previously approved applications. Neither we nor, we believe, any of our employees have ever been subject to debarment.

*Patent and Non-Patent Exclusivity Periods*

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA to secure approval of a generic version of this first, or listed, drug, or an NDA that relies upon the data in the application for which the patents are listed, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) the later applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder or the NDA for the listed drug of the bases upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. If an infringement suit is filed, the FDA may not approve the later application for 30 months or such time as the court may order.

In addition, the holder of the NDA for the listed drug is entitled to certain non-patent exclusivity before which the FDA cannot approve an application for a competitive product. If the listed drug is a new chemical entity, the FDA may not accept for review any application for five years; if it is not a new chemical entity, the FDA may not approve a competitive application before expiration of three years. Certain other periods of exclusivity may be available if the listed drug is indicated for use in a rare disease or is studied for pediatric indications.

*Quality Assurance Requirements*

The FDA enforces regulations to assure that the methods used in, and facilities and controls used for, the manufacture, processing, packing and holding of drugs conform with current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality, purity and safety characteristics required of them. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not meet cGMP requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and verified in a subsequent inspection. In addition, manufacturers of active pharmaceutical ingredients, or APIs, used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when an API manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations and financial condition.

The FDA also conducts periodic inspections of facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations and financial condition. Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or require product recalls and seek to enjoin a product s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP

requirements, sanctions may be imposed that include preventing the company from receiving the necessary licenses to export its products and classifying the company as an unacceptable supplier , thereby disqualifying the company from selling products to federal agencies.

We believe that we and our suppliers and outside manufacturers are currently in compliance with cGMP requirements.

*Other FDA Matters*

If there are any modifications to an approved drug, including changes in indication, manufacturing process or labeling or a change in a manufacturing facility, an application seeking approval of such changes must be submitted to the FDA or other regulatory authority. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. Failure to adhere to such requirements can result in regulatory actions that could have a material adverse effect on our business, results of operations and financial condition.

*Drug Enforcement Agency*

We also sell products that are controlled substances as defined in the Controlled Substances Act, which establishes certain security and record keeping requirements administered by the U.S. Drug Enforcement Agency, or DEA. The DEA is concerned with the control of registered handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of scheduled substances we can obtain for clinical trials and commercial distribution is limited by the DEA.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture or distribute controlled substances must be registered to perform these activities and have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

We and our third-party API suppliers, dosage form manufacturers, distributors and researchers have necessary registrations, and we believe all registrants operate in conformity with applicable requirements.

*Government Benefit Programs*

Medicaid, Medicare and other reimbursement legislation or programs govern reimbursement levels, including requiring that all pharmaceutical companies rebate to individual states a percentage of their net sales arising from Medicaid-reimbursed products. The federal and/or state governments may continue to enact measures in the future aimed at reducing the cost of prescription pharmaceuticals to the public. We cannot predict the nature of such measures or their impact on our profitability and cash flows.

**Service Agreements**

We contract with various third parties to provide certain critical services including manufacturing, sales representatives, warehousing, distribution, customer service, certain financial functions, certain research and development activities and medical affairs.

*Third Party Manufacturing/ Supply Agreements*

We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods including, among others, Bristol-Myers Squibb (f/k/a DuPont Pharmaceuticals), Novartis Consumer Health and Teikoku Seiyaku Pharmaceuticals. While we generally have not had difficulty obtaining finished goods, raw materials and components from suppliers in the past, we cannot assure you that these necessary finished goods, raw materials and components will continue to be available on commercially acceptable terms in the future. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and results of operations. In addition, we have incurred and expect to continue to incur significant costs in obtaining the regulatory approvals and taking other steps necessary to begin commercial production at other manufacturers, including Novartis, of all our products currently manufactured at Bristol-Myers Squibb. A description of the material terms of the material third party manufacturing/ supply contracts follows:

*Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals).* Bristol-Myers Squibb (f/k/a DuPont Pharmaceuticals) currently manufactures a significant number of our brand and generic pharmaceutical products. Bristol-Myers Squibb manufactures certain of the products that we purchased from DuPont Pharmaceuticals as a result of our August 1997 acquisition from DuPont Pharmaceuticals, as well as some of our new products. The products are manufactured at either the Bristol-Myers Squibb facility in Garden City, New York or the Bristol-Myers Squibb facility in Manati, Puerto Rico. Both of these facilities are FDA- and DEA-approved. Under the terms of this agreement, we are able to introduce the manufacture of new products that we have developed in those plants. For these manufacturing services, we currently pay Bristol-Myers Squibb compensation in the form of (1) a fixed amount to cover Bristol-Myers Squibb s fixed manufacturing costs for both manufacturing facilities, (2) an amount, adjusted on an annual basis, to cover Bristol-Myers Squibb s variable manufacturing costs for our products in both facilities and (3) an additional fee, paid annually, based upon a predetermined formula.

In addition to manufacturing services, Bristol-Myers Squibb currently provides other ancillary services to us in connection with the manufacture of our products such as raw material procurement, product development, inventory management and quality control services. Compensation for these services is included in the compensation for manufacturing services. The initial term of this agreement is five years, expiring on August 26, 2002, and is renewable, at our option, for a period of time not to exceed five years (through August 2007) with pricing terms to be negotiated. We have begun discussions with Bristol-Myers Squibb concerning arrangements to manufacture certain of our products following the expiration of the initial term in August 2002. If Bristol-Myers Squibb determines to sell or otherwise transfer either the Garden City plant facility or the Manati plant facility and we determine that the acquirer of such facility would not be an acceptable manufacturer of our products, Bristol-Myers Squibb shall implement, at its cost, appropriate arrangements for the manufacture and supply of the products elsewhere.

*Teikoku Seiyaku Co., Ltd.* Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. We are required to purchase, on an annual basis, a minimum amount of product from Teikoku. The purchase price for the product is equal to a predetermined amount per unit of product. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc. or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

*Novartis Consumer Health, Inc.* On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual

basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement has a five-year term, with automatic five-year renewals thereafter. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

*Mallinckrodt Inc.* Under the terms of this agreement, Mallinckrodt will manufacture and supply to us narcotic active drug substances, in bulk form, and upon the expiration of Mallinckrodt s existing supply agreement with Bristol-Myers Squibb, raw materials for inclusion in our controlled substance pharmaceutical products. We are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement for a material breach.

In addition, under a separate agreement, Mallinckrodt exclusively manufactures and supplies to us a narcotic active drug substance that is not covered under the previously discussed Mallinckrodt agreement. We are required to purchase a fixed percentage of our annual requirements of this narcotic active drug substance from Mallinckrodt. The purchase price of the substance is a fixed amount that may be adjusted annually in the event of Mallinckrodt product cost increases. The term of this agreement is April 1, 1998 until June 30, 2004, as extended pursuant to an amendment, dated as of May 8, 2000, with an automatic renewal provision for unlimited successive one-year periods. This agreement may also be terminated for material breach by either party.

*Other Service Agreements*

In addition to the long-term manufacturing agreements described above, we have agreements with (1) Livingston Healthcare Services, Inc. (n/k/a UPS Supply Chain Management, Inc.) for customer service support, warehouse and distribution services and certain financial functions, (2) Kunitz and Associates Inc. for medical affairs and (3) Ventiv Health U.S. Sales Inc. for sales. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations would have a materially adverse effect on our business, financial condition and results of operations.

A description of the material terms of these agreements follows:

*Livingston Healthcare Services Inc. (n/k/a UPS Supply Chain Management, Inc.)* Under the terms of this agreement, we appointed Livingston to provide customer service support, chargeback processing, accounts receivables management and warehouse and distribution services for our products in the United States. During the term of the agreement, the Livingston personnel responsible for providing our customer service, chargeback processing and accounts receivable management services may not provide these services to any third party for any third party products which directly compete with our products covered under the agreement. We pay Livingston a (1) start-up fee, payable in three installments, (2) a fixed monthly fee for all services and (3) certain miscellaneous out-of-pocket expenses, which, in the aggregate, may, depending on the facts and circumstances at the time, represent material costs to us. For the year ended December 31, 2001, these fees and expenses were approximately $5.0 million. The term of the agreement for customer service support and chargeback processing services is February 1, 2000 to January 31, 2003; for accounts receivable services, February 1, 2000 to January 31, 2003; and for warehouse and distribution services, February 1, 2000 to February 28, 2005. The agreement may be renewed upon mutual agreement of the parties. The agreement may be terminated for material breach by us, with prior notice: (1) for a sale of our company or a sale of substantially all of our business; by us, with prior notice, for a change in our stock ownership or company control; (2) if we decide to have these services provided in-house or by an affiliate or (3) if Livingston fails to

provide additional storage space for our products upon request. In the event of termination under certain circumstances, we are required to pay Livingston for certain capital investments and wind-down expenses.

*Kunitz and Associates Inc.* Under the terms of the agreement, we appointed Kunitz as our exclusive provider in the United States of pharmacovigilance, medical communications, product information support, adverse drug experience surveillance and medical literature search support, with respect to all of our products. During the term of this agreement, Kunitz may not provide identical or similar services to or for any third party whose products directly compete with our products in the prescription pain management therapeutic category. For these services, we pay Kunitz a fixed amount, in equal monthly installments. This agreement will expire on July 31, 2002, unless we exercise our option to renew the agreement for up to two successive one-year periods through July 31, 2004. The agreement may be terminated by either party for material breach or by us, with notice, for no reason.

*Ventiv Health U.S. Sales Inc.* Under the terms of this agreement, a team of Ventiv professional sales representatives, under our management s direction, exclusively promotes certain of our products to healthcare professionals in the United States. The term of this agreement is until December 31, 2003, but will automatically renew for one-year periods thereafter. The agreement may be terminated by either party for material breach, by us (with 90 days notice) for no reason or by Ventiv (with 180 days notice) for no reason. Under the agreement, we reserve the option to hire all of these sales representatives and managers as our full-time employees at any time.

**Licenses and Collaboration Agreements**

We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities.

*Virginia Commonwealth University.* We have licensed from Virginia Commonwealth University certain patents and pending patent applications in the field of pain management. These include patents covering MorphiDex® and other combinations of the NMDA-receptor antagonist, dextromethorphan, with opioids. Under this license, we are required to pay royalties equal to 4% of sales of products resulting from the licensed patents. In addition, we will pay Virginia Commonwealth University 50% of royalty payments received from any sublicensees until such payments total $500,000 for a given year, 33% until the payments total an additional $500,000 for such year and 25% thereafter. This license lasts until the underlying patents expire.

*Penwest Pharmaceuticals.* In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest s patent-protected proprietary technology, for commercial sale worldwide. Under the terms of this agreement, we are currently developing an opioid product for the treatment of pain. We currently share on an equal basis the costs and profits of products developed under this agreement. At this point in time, we cannot predict the cost of this agreement. We have exclusive U.S. marketing rights with respect to products developed under this collaboration, subject to the terms and conditions contained in this agreement. See Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

*Hind Healthcare Inc.* In November 1998, we entered into a license agreement with Hind Healthcare Inc. for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. We paid Hind up-front fees and milestone payments on the occurrence of certain events. From now until the shorter of (1) the life of the last-to-expire patent license pursuant to this license agreement and (2) November 20, 2011, we will pay Hind non-refundable royalties, including a minimum annual royalty of at least $500,000 per year, on net sales of the product in the future. Because these royalty payments are based on the net sales of the product, the maximum cost of these royalty payments is uncertain at this time. During 2001, we accrued $3.3 million for this royalty. Either party may terminate this agreement for material breach and we may terminate it immediately upon termination of our supply agreement with Teikoku. In September 1999, we launched Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

**Environmental Matters**

Our operations are subject to substantial and evolving federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances. We believe that our facilities and the facilities of our third party service providers are in substantial compliance with all provisions of federal, state and local laws concerning the environment and do not believe that future compliance with these provisions will have a material adverse effect on our financial condition or results of operations.

**Summary of Recent Transactions**

On August 1, 2001, we moved into our new corporate headquarters at 100 Painters Drive, Chadds Ford, Pennsylvania. We lease this space from Painters Crossing One Associates, L.P. See Item 2. Properties.

On October 17, 2001, we sold 11,400,000 additional shares of common stock at a price of $8.00 per share in a follow-on public offering. On November 16, 2001, we closed the sale of an additional 1,525,000 shares of common stock, at $8.00 per share, in connection with the exercise by the underwriters of their over-allotment option in connection with this public offering. A total of 12,925,000 shares common stock were issued and sold by the Company in this offering for a total of $96.2 million in net proceeds.

On October 29, 2001, we used $84.9 million of the net proceeds from the recently completed public offering plus $16.1 million from our cash balance to repay in full the term loans under the then current credit facility. On December 21, 2001, we amended and restated our credit facility. The details of this amendment and restatement are set forth below. See Description of Credit Facility.

On December 5, 2001, we commenced a tender offer to purchase up to 13,500,000 of our outstanding Class A Transferable Warrants (Nasdaq: ENDPW) and any and all of our outstanding Class B Non-Transferable Warrants. This tender offer expired at midnight on January 25, 2002. We accepted an aggregate of 8,576,762 Class A Warrants and 8,500 Class B Warrants for payment at a purchase price of $0.75 per warrant, or approximately $6.4 million in the aggregate. We used cash on hand to finance the purchase of tendered warrants. Following of the purchase of these warrants by us, approximately 9.2 million Class A Warrants and approximately 18,500 Class B Warrants remained outstanding as of January 28, 2002.

**Description of Credit Facility**

On August 26, 1997, we entered into a credit agreement with a number of lenders and The Chase Manhattan Bank (n/k/a JPMorgan Chase Bank), as administrative agent. On October 29, 2001, we repaid in full the $101.1 million of term loans that were outstanding thereunder, and on December 21, 2001, we amended and restated this credit agreement. As of December 31, 2001, no amounts were outstanding under the credit agreement.

Under the credit agreement, we have the ability to borrow on a revolving basis up to $75.0 million. The revolving loans have a final maturity of December 21, 2006. The credit agreement also provides for a delayed draw term loan that must be utilized, if at all, by August 26, 2002 solely for the purpose of paying off the outstanding promissory notes that are payable to Bristol-Myers Squibb. The aggregate principal amount of this term loan is $25.0 million. The term loan, once borrowed and repaid, may not be reborrowed, and it has a final maturity date of December 21, 2006. As of December 31, 2001, we have not borrowed under either the revolving loans or the term loan.

These loans bear interest at an agreed-upon spread over the applicable base rate (as defined in the credit agreement) or over the London Interbank Offered Rate. The loans outstanding under the credit agreement are secured by a first priority security interest in substantially all of our assets. These loans are subject to mandatory repayment in limited circumstances. Voluntary prepayments of these loans and voluntary reductions of the credit facility are permitted, in whole or in part, at our option in minimum principal amounts, without premium or penalty, subject to reimbursement of the lenders costs under specified circumstances.

The credit agreement contains representations and warranties, covenants, events of default and other provisions customarily found in similar agreements.

**Employees**

As of December 31, 2001, we had 167 employees, of which 52 are engaged in research and development, 15 in regulatory work, 30 in sales and marketing, 18 in quality assurance and 52 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

**Dividend Policy**

We have never paid cash dividends on our common stock. Furthermore, the payment of cash dividends from earnings is currently restricted by our credit facility. Assuming removal of this restriction, the payment of cash dividends is subject to the discretion of our board of directors and will be dependent on many factors, including our earnings, capital needs and general financial condition. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance the expansion of our business.

**Item 2.** ***Properties***

We lease all of our properties. Of these, the most significant are our research and development facility located in Garden City, New York and our corporate headquarters in Chadds Ford, Pennsylvania. Through the acquisition of Algos in July 2000, we also acquired a lease of the former corporate headquarters of Algos in Neptune, New Jersey. This lease was terminated on April 30, 2001. A description of the material terms of each of the agreements pertaining to these properties follows:

**Garden City, New York**

*Bristol-Myers Squibb Company (f/k/a DuPont Pharmaceuticals) Lease Agreement.* Under this agreement, we lease a laboratory and office building from Bristol-Myers Squibb, which is located at Bristol-Myers Squibb s Garden City, New York manufacturing facility. We may use these facilities for the research and development of our pharmaceutical products. The lease is not assignable by us without the consent of Bristol-Myers Squibb. The lease may be terminated (1) by us, if substantial premise alteration changes are required in order to comply with government regulations, (2) by Bristol-Myers Squibb, for tenant damage and destruction to the premises and (3) as a result of arbitration between the parties. The term of the lease is five years, expiring August 26, 2002 and is renewable at our option, provided the related manufacturing and supply agreement between the parties has been renewed, for an additional five-year period or successive one-year periods through August 2007.

**Chadds Ford, Pennsylvania**

*Route 202-Concord Partners (formerly Northstar) Lease Agreement.* Under this agreement, we lease office space in Chadds Ford, Pennsylvania that had been used for our headquarters and administrative functions until August 2001. The lease commenced on October 1, 1997, for an initial term of five years. The annual base rent is adjusted annually by a fixed percentage. After the initial term, the parties may extend this lease for another five-year term. The lease may be assigned or the premises sublet with the landlord s written consent. We amended this lease on December 16, 1997, January 6, 1999, November 23, 1999 and November 8, 2000, in order for us to acquire additional office space in the same building for an additional fee. Since we moved to our new headquarters in August 2001, we intend to allow this lease to lapse on October 1, 2002, in accordance with its terms.

*Painters Crossing One Associates, L.P. Lease Agreement.* On May 5, 2000, we entered into a ten-year lease with Painters Crossing One Associates, L.P. pursuant to which Painters Crossing leases to us a building comprised of approximately 47,756 square feet located in Chadds Ford, Pennsylvania. By amendment dated February 26, 2001, this lease commenced on August 1, 2001 and will end on August 31, 2010. However, we, at our discretion, have the right to terminate this lease at the end of the fifth year, by providing two years notice

and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

**Neptune, New Jersey**

*Commercial Realty & Resources Corp. Lease.* Through our acquisition of Algos in July 2000, we had acquired the lease of the former Algos corporate headquarters in Neptune, New Jersey. On April 30, 2001, we terminated this lease and obtained from the landlord a full and final release from any and all obligations thereunder.

**Item 3.** ***Legal Proceedings***

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue Frederick s OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent versions of Purdue Frederick s OxyContin®, 10mg and 20mg strengths, infringe the same three patents. This suit arose from EPI having amended its earlier ANDA on February 9, 2001 to add bioequivalent versions of the 10mg and 20mg strengths of OxyContin®. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin®, 80mg strength, infringes the same three patents. This suit arose from EPI having amended its earlier ANDA on July 30, 2001 to add the bioequivalent version of the 80mg strength of OxyContin®.

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA s Orange Book as covering these strengths of OxyContin®. EPI has pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI s formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI has also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability. However, we cannot make any assurances as to the outcome of this patent challenge. Purdue Frederick was granted a preliminary injunction (Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 98 F. Supp. 2d 362 (SDNY 2000)), which decision was affirmed on appeal (Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359 (Fed. Cir. 2001)), against a different manufacturer based on the same patents that are being asserted against us and EPI, and in the same court in which Purdue Frederick sued. We believe the defenses rejected in the preliminary injunction decision and in the appellate decision do not substantially impact the principal defenses raised by us and EPI.

On November 15, 2001, SmithKline Beecham Corporation (and related companies) filed suit against EPI in the U.S. District Court for the Eastern District of Pennsylvania alleging that EPI s bioequivalent version of SmithKline s Paxil®, 40 mg strength, infringes five of its patents. The FDA accepted EPI s ANDA submission for a bioequivalent version of SmithKline s Paxil®, 40 mg strength, earlier in 2001. In this ANDA, EPI made the required Paragraph IV certification against all of the SmithKline patents listed in the FDA s Orange Book as covering Paxil®. Paxil® is indicated for the treatment of depression, obsessive compulsive disorder and panic disorder. Although we believe the patents asserted by SmithKline Beecham are invalid and/or not infringed, no assurance can be given as to the outcome of this patent challenge process.

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

On November 15, 2001, EPI was named, along with ten other pharmaceutical companies, as a defendant in a class action lawsuit filed by Bennie Toombs in the United States District Court for the Western District of Louisiana. According to the complaint, each of the defendant pharmaceutical companies had allegedly manufactured and sold products containing phenylpropanolamine (PPA). The complaint alleges that the defendants failed to adequately warn plaintiff of the hazards of the use of the subject products containing PPA and that as a result of this failure to warn, plaintiffs suffered injury. The action has been transferred by order of the United States Judicial Panel on Multidistrict Litigation to the Western District of Washington, where it has been consolidated for pretrial proceedings with other cases involving claims against manufacturers of PPA-containing products. EPI is not a party to any of these other actions and intends to vigorously defend itself in the *Toombs* litigation.

In addition to the above, the Company is involved in, or has been involved in, arbitrations or legal proceedings that arise from the normal course of its business. The Company cannot predict the timing or outcome of these claims and proceedings. Currently, the Company is not involved in any arbitration and/or legal proceeding that it expects to have a material effect on its business, financial condition or results of operations and cash flows.

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

No matters were submitted to a vote of security holders during the fourth quarter of our fiscal year ended December 31, 2001.

**Item 4A.** ***Executive Officers of the Registrant***

Set forth below is information regarding each current executive officer of Endo:

| Name | Age | Position and Offices |
|---|---|---|
| Carol A. Ammon | 51 | President, Chief Executive Officer, Chairman and Director |
| Mariann T. MacDonald | 54 | Executive Vice President, Operations |
| Jeffrey R. Black | 37 | Senior Vice President, Chief Financial Officer and Treasurer |
| Peter A. Lankau | 49 | Senior Vice President, U.S. Business |
| David A.H. Lee, M.D., Ph.D. | 52 | Senior Vice President, Research & Development |
| Caroline B. Manogue | 33 | Senior Vice President, General Counsel & Secretary |

CAROL A. AMMON, 51, is President, Chief Executive Officer, Chairman and Director of Endo. Prior to joining Endo, Ms. Ammon was the President of DuPont Merck s U.S. Pharmaceuticals Division from 1996 through 1997, and from 1993 through 1995 she was the President of Endo Laboratories, L.L.C. She also serves as a director on the boards of the Christiana Care Health System and the St. Louis School of Pharmacy in St. Louis, Missouri.

MARIANN T. MACDONALD, 54, is Executive Vice President, Operations of Endo. Prior to joining Endo, Ms. MacDonald was Vice President of Business Information, Training, Administration & Technology for the U.S. Pharmaceuticals Division of DuPont Merck from 1996 to 1997 and Vice President of Operations for Endo Laboratories, L.L.C. from 1995 to 1996. From 1993 to 1995, Ms. MacDonald held various management positions in DuPont Merck.

JEFFREY R. BLACK, 37, is Senior Vice President, Chief Financial Officer and Treasurer of Endo. Prior to joining Endo, Mr. Black became a Partner in June 1997 with Deloitte & Touche LLP in the New York Merger and Acquisition Services Group, after joining that firm in 1986.

PETER A. LANKAU, 49, is Senior Vice President, U.S. Business of Endo. Prior to joining Endo in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales U.S. Pharmaceuticals for Rhone Poulenc Rorer, Inc. from 1996 to 1999, based in Collegeville, Pennsylvania. Prior to 1996, Mr. Lankau was Executive Director, Strategy and

(2) the close of trading on any trading day for the underlier or any successor underlier means the scheduled closing time of the relevant stock exchanges with respect to the securities underlying the underlier or successor underlier on such trading day; provided that, if the actual closing time of the regular trading session of any such relevant stock exchange is earlier than its scheduled closing time on such trading day, then (x) for purposes of clauses (A) and (C) of the definition of market disruption event above, with respect to any security underlying the underlier or successor underlier for which such relevant stock exchange is its relevant stock exchange, the close of trading means such actual closing time and (y) for purposes of clauses (B) and (D) of the definition of market disruption event above, with respect to any futures or options contract relating to the underlier or successor underlier, the close of trading means the latest actual closing time of the regular trading session of any of the relevant stock exchanges, but in no event later than the scheduled closing time of the relevant stock exchanges;

(3) the scheduled closing time of any relevant stock exchange or related futures or options exchange on any trading day for the underlier or any successor underlier means the scheduled weekday closing time of such relevant stock exchange or related futures or options exchange on such trading day, without regard to after hours or any other trading outside the regular trading session hours; and

(4) an exchange business day means any trading day for the underlier or any successor underlier on which each relevant stock exchange for the securities underlying the underlier or any successor underlier and each related futures or options exchange are open for trading during their respective regular trading sessions, notwithstanding any such relevant stock exchange or related futures or options exchange closing prior to its scheduled closing time.

If a market disruption event occurs or is continuing on the determination date, then the determination date will be postponed to the first succeeding trading day on which a market disruption event has not occurred and is not continuing; however, if such first succeeding trading day has not occurred as of the eighth trading day after the originally scheduled determination date, that eighth trading day shall be deemed to be the determination date. If the determination date has been postponed eight trading days after the originally scheduled determination date and a market disruption event occurs or is continuing on such eighth trading day, the calculation agent will determine the closing level of the underlier on such eighth trading day in accordance with the formula for and method of calculating the closing level of the underlier last in effect prior to commencement of the market disruption event, using the closing price (or, with respect to any relevant security, if a market disruption event has occurred with respect to such security, its good faith estimate of the value of such security at the scheduled closing time of the relevant stock exchange for such security or, if earlier, the actual closing time of the regular trading session of such relevant stock exchange) on such date of each security included in the underlier. As used herein, closing price means, with respect to any security on any date, the relevant stock exchange traded or quoted price of such security as of the scheduled closing time of the relevant stock exchange for such security or, if earlier, the actual closing time of the regular trading session of such relevant stock exchange.

**Adjustments to the Underlier**

If at any time the sponsor or publisher of the underlier (the underlier sponsor ) makes a material change in the formula for or the method of calculating the underlier, or in any other way materially modifies the underlier (other than a modification prescribed in that formula or method to maintain the underlier in the event of changes in constituent stock and capitalization and other routine events), then, from and after that time, the calculation agent will, at the close of business in New York, New York, on each date that the closing level of the underlier is to be calculated, calculate a substitute closing level of the underlier in accordance with the formula for and method of calculating the underlier last in effect prior to the change, but using only those securities that comprised the underlier immediately prior to that change. Accordingly, if the method of calculating the underlier is modified so that the level of the underlier is a

fraction or a multiple of what it would have been if it had not been modified, then the calculation agent will adjust the underlier in order to arrive at a level of the underlier as if it had not been modified.

**Discontinuance of the Underlier**

If the underlier sponsor discontinues publication of the underlier, and the underlier sponsor or another entity publishes a successor or substitute equity index that the calculation agent determines, in its sole discretion, to be comparable to the underlier (a successor underlier), then, upon the calculation agent s notification of that determination to the trustee and Wells Fargo, the calculation agent will substitute the successor underlier as calculated by the relevant underlier sponsor or any other entity and calculate the final underlier level as described above. Upon any selection by the calculation agent of a successor underlier, Wells Fargo will cause notice to be given to holders of the securities.

In the event that the underlier sponsor discontinues publication of the underlier prior to, and the discontinuance is continuing on, the determination date and the calculation agent determines that no successor underlier is available at such time, the calculation agent will calculate a substitute closing level for the underlier in accordance with the formula for and method of calculating the underlier last in effect prior to the discontinuance, but using only those securities that comprised the underlier immediately prior to that discontinuance. If a successor underlier is selected or the calculation agent calculates a level as a substitute for the underlier, the successor underlier or level will be used as a substitute for the underlier for all purposes, including the purpose of determining whether a market disruption event exists.

If on the determination date the underlier sponsor fails to calculate and announce the level of the underlier, the calculation agent will calculate a substitute closing level of the underlier in accordance with the formula for and method of calculating the underlier last in effect prior to the failure, but using only those securities that comprised the underlier immediately prior to that failure; *provided* that, if a market disruption event occurs or is continuing on such day, then the provisions set forth above under Market Disruption Events shall apply in lieu of the foregoing.

Notwithstanding these alternative arrangements, discontinuance of the publication of, or the failure by the underlier sponsor to calculate and announce the level of, the underlier may adversely affect the value of the securities.

**Events of Default and Acceleration**

If an event of default with respect to the securities has occurred and is continuing, the amount payable to a holder of a security upon any acceleration permitted by the securities, with respect to each security, will be equal to the cash settlement amount, calculated as provided herein. The cash settlement amount will be calculated as though the date of acceleration were the determination date.

**The S&P 500 Index**

The S&P 500 Index is an equity index that is intended to provide an indication of the pattern of common stock price movement in the large capitalization segment of the United States equity market. Wells Fargo & Company is one of the companies currently included in the S&P 500 Index. See Description of Equity Indices The S&P 500® Index in the accompanying market measure supplement for additional information about the S&P 500 Index. In addition to the criteria for addition to the S&P 500 Index set forth in the accompanying market measure supplement, a company must have a primary listing to its common stock on the NYSE, NYSE Arca, NYSE MKT, NASDAQ Global Select Market, NASDAQ Select Market, NASDAQ Capital Market, Bats BZX, Bats BYX, Bats EDGA or Bats EDGX.

**Historical Information**

We obtained the closing levels set forth in the graph below from Bloomberg Financial Markets without independent verification.

The historical performance of the underlier should not be taken as an indication of the future performance of the underlier during the term of the securities.

The following graph sets forth the daily closing levels of the underlier for each day in the period from January 1, 2006 through October 6, 2016. The closing level on October 6, 2016 was 2,160.77.

**Benefit Plan Investor Considerations**

Each fiduciary of a pension, profit-sharing or other employee benefit plan to which Title I of the Employee Retirement Income Security Act of 1974 ( ERISA ) applies (a plan ), should consider the fiduciary standards of ERISA in the context of the plan s particular circumstances before authorizing an investment in the securities. Accordingly, among other factors, the fiduciary should consider whether the investment would satisfy the prudence and diversification requirements of ERISA and would be consistent with the documents and instruments governing the plan. When we use the term holder in this section, we are referring to a beneficial owner of the securities and not the record holder.

Section 406 of ERISA and Section 4975 of the Code prohibit plans, as well as individual retirement accounts and Keogh plans to which Section 4975 of the Code applies (also plans ), from engaging in specified transactions involving plan assets with persons who are parties in interest under ERISA or disqualified persons under the Code (collectively parties in interest ) with respect to such plan. A violation of those prohibited transaction rules may result in an excise tax or other liabilities under ERISA and/or Section 4975 of the Code for such persons, unless statutory or administrative exemptive relief is available. Therefore, a fiduciary of a plan should also consider whether an investment in the securities might constitute or give rise to a prohibited transaction under ERISA and the Code.

Employee benefit plans that are governmental plans, as defined in Section 3(32) of ERISA, certain church plans, as defined in Section 3(33) of ERISA, and foreign plans, as described in Section 4(b)(4) of ERISA (collectively, Non-ERISA Arrangements ), are not subject to the requirements of ERISA, or Section 4975 of the Code, but may be subject to similar rules under other applicable laws or regulations ( Similar Laws ).

We and our affiliates may each be considered a party in interest with respect to many plans. Special caution should be exercised, therefore, before the securities are purchased by a plan. In particular, the fiduciary of the plan should consider whether statutory or administrative exemptive relief is available. The U.S. Department of Labor has issued five prohibited transaction class exemptions ( PTCEs ) that may provide exemptive relief for direct or indirect prohibited transactions resulting from the purchase or holding of the securities. Those class exemptions are:

PTCE 96-23, for specified transactions determined by in-house asset managers;

PTCE 95-60, for specified transactions involving insurance company general accounts;

PTCE 91-38, for specified transactions involving bank collective investment funds;

PTCE 90-1, for specified transactions involving insurance company separate accounts; and

PTCE 84-14, for specified transactions determined by independent qualified professional asset managers.

In addition, Section 408(b)(17) of ERISA and Section 4975(d)(20) of the Code provide an exemption for transactions between a plan and a person who is a party in interest (other than a fiduciary who has or exercises any discretionary authority or control with respect to investment of the plan assets involved in the transaction or renders investment advice with respect thereto) solely by reason of providing services to the plan (or by reason of a relationship to such a service provider), if in connection with the transaction of the plan receives no less, and pays no more, than adequate consideration (within the meaning of Section 408(b)(17) of ERISA).

Any purchaser or holder of the securities or any interest in the securities will be deemed to have represented by its purchase and holding that either:

no portion of the assets used by such purchaser or holder to acquire or purchase the securities constitutes assets of any plan or Non-ERISA Arrangement; or

the purchase and holding of the securities by such purchaser or holder will not constitute a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code or similar violation under any Similar Laws.

Due to the complexity of these rules and the penalties that may be imposed upon persons involved in non-exempt prohibited transactions, it is particularly important that fiduciaries or other persons considering purchasing the securities on behalf of or with plan assets of any plan consult with their counsel regarding the potential consequences under ERISA and the Code of the acquisition of the securities and the availability of exemptive relief.

The securities are contractual financial instruments. The financial exposure provided by the securities is not a substitute or proxy for, and is not intended as a substitute or proxy for, individualized investment management or advice for the benefit of any purchaser or holder of the securities. The securities have not been designed and will not be administered in a manner intended to reflect the individualized needs and objectives of any purchaser or holder of the securities.

Each purchaser or holder of the securities acknowledges and agrees that:

(i) the purchaser or holder or its fiduciary has made and shall make all investment decisions for the purchaser or holder and the purchaser or holder has not relied and shall not rely in any way upon us or our affiliates to act as a fiduciary or adviser of the purchaser or holder with respect to (a) the design and terms of the securities, (b) the purchaser or holder s investment in the securities, or (c) the exercise of or failure to exercise any rights we have under or with respect to the securities;

(ii) we and our affiliates have acted and will act solely for our own account in connection with (a) all transactions relating to the securities and (b) all hedging transactions in connection with our obligations under the securities;

(iii) any and all assets and positions relating to hedging transactions by us or our affiliates are assets and positions of those entities and are not assets and positions held for the benefit of the purchaser or holder;

(iv) our interests may be adverse to the interests of the purchaser or holder; and

(v) neither we nor any of our affiliates is a fiduciary or adviser of the purchaser or holder in connection with any such assets, positions or transactions, and any information that we or any of our affiliates may provide is not intended to be impartial investment advice.

Purchasers of the securities have the exclusive responsibility for ensuring that their purchase, holding and subsequent disposition of the securities does not violate the fiduciary or prohibited transaction rules of ERISA, the Code or any Similar Law. Nothing herein shall be construed as a representation that an investment in the securities would be appropriate for, or would meet any or all of the relevant legal requirements with respect to investments by, plans or Non-ERISA Arrangements generally or any particular plan or Non-ERISA Arrangement.

**United States Federal Tax Considerations**

The following is a discussion of the material U.S. federal income and certain estate tax consequences of the ownership and disposition of the securities. It applies to you only if you purchase a security for cash in the initial offering at the issue price, which is the first price at which a substantial amount of the securities is sold to the public, and hold the security as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the Code ). It does not address all of the tax consequences that may be relevant to you in light of your particular circumstances or if you are an investor subject to special rules, such as:

a financial institution;

a regulated investment company ;

a tax-exempt entity, including an individual retirement account or Roth IRA ;

a dealer or trader subject to a mark-to-market method of tax accounting with respect to the securities;

a person holding a security as part of a straddle or conversion transaction or who has entered into a constructive sale with respect to a security;

a U.S. holder (as defined below) whose functional currency is not the U.S. dollar; or

an entity classified as a partnership for U.S. federal income tax purposes.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds the securities, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partnership holding the securities or a partner in such a partnership, you should consult your tax adviser as to your particular U.S. federal tax consequences of holding and disposing of the securities.

We will not attempt to ascertain whether any of the issuers of the underlying stocks of the underlier (the underlying stocks ) is treated as a U.S. real property holding corporation ( USRPHC ) within the meaning of Section 897 of the Code or as a passive foreign investment company ( PFIC ) within the meaning of Section 1297 of the Code. If any of the issuers of the underlying stocks were so treated, certain adverse U.S. federal income tax consequences might apply to you, in the case of a USRPHC if you are a non-U.S. holder (as defined below) and in the case of a PFIC if you are a U.S. holder (as defined below), upon the sale, exchange or other disposition of the securities. You should refer to information filed with the Securities and Exchange Commission or another governmental authority by the issuers of the underlying stocks and consult your tax adviser regarding the possible consequences to you if any of the issuers of the underlying stocks is or becomes a USRPHC or PFIC.

This discussion is based on the Code, administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations, all as of the date of this pricing supplement, changes to any of which subsequent to the date of this pricing supplement may affect the tax consequences described herein, possibly with retroactive effect. This discussion does not address the effects of any applicable state, local or non-U.S. tax laws or the potential application of the alternative minimum tax or of the Medicare tax on investment income. You should consult your tax adviser concerning the application of U.S. federal income and estate tax laws to your particular situation (including the possibility of alternative treatments of the securities), as well as any tax consequences arising under the laws of any state, local or non-U.S. jurisdiction.

**Tax Treatment of the Securities**

In the opinion of our counsel, Davis Polk & Wardwell LLP, which is based on current market conditions, a security should be treated as a prepaid derivative contract that is an open transaction for U.S. federal income tax purposes. By purchasing a security, you agree (in the absence of an administrative determination or judicial ruling to the contrary) to this treatment.

**Due to the absence of statutory, judicial or administrative authorities that directly address the U.S. federal tax treatment of the securities or similar instruments, significant aspects of the treatment of an investment in the securities are uncertain. We do not plan to request a ruling from the IRS, and the IRS or a court might not agree with the treatment described below. Accordingly, you should consult your tax adviser regarding all aspects of the U.S. federal income and estate tax consequences of an investment in the securities. Unless otherwise indicated, the following discussion is based on the treatment of the securities as prepaid derivative contracts that are open transactions.**

**Tax Consequences to U.S. Holders**

This section applies only to U.S. holders. You are a U.S. holder if you are a beneficial owner of a security that is, for U.S. federal income tax purposes:

a citizen or individual resident of the United States;

a corporation created or organized in or under the laws of the United States, any state therein or the District of Columbia; or

an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

*Tax Treatment Prior to Maturity*. You should not be required to recognize income over the term of the securities prior to maturity, other than pursuant to a sale, exchange or retirement as described below.

*Sale, Exchange or Retirement of the Securities*. Upon a sale, exchange or retirement of the securities, you should recognize gain or loss equal to the difference between the amount realized on the sale, exchange or retirement and your tax basis in the securities that are sold, exchanged or retired. Your tax basis in the securities should equal the amount you paid to acquire them. This gain or loss should be long-term capital gain or loss if at the time of the sale, exchange or retirement you held the securities for more than one year, and short-term capital gain or loss otherwise. Long-term capital gains recognized by non-corporate U.S. holders are generally subject to taxation at reduced rates. The deductibility of capital losses is subject to certain limitations.

***Possible Alternative Tax Treatments of an Investment in the Securities***

Alternative U.S. federal income tax treatments of the securities are possible that, if applied, could materially and adversely affect the timing and/or character of income, gain or loss with respect to them. It is possible, for example, that the securities could be treated as debt instruments governed by Treasury regulations relating to the taxation of contingent payment debt instruments. In that case, regardless of your method of tax accounting for U.S. federal income tax purposes, you would be required to accrue income based on our comparable yield for similar non-contingent debt, determined as of the time of issuance of the securities, in each year that you held the securities, even though we are not required to make any payment with respect to the securities prior to maturity. In addition, any gain on the sale, exchange or retirement of the securities would be treated as ordinary income.

Other possible U.S. federal income tax treatments of the securities could also affect the timing and character of income or loss with respect to the securities. In 2007, the U.S. Treasury Department and the IRS released a notice requesting comments on the U.S. federal income tax treatment of prepaid forward contracts and similar instruments. The notice focuses in particular on whether to require holders of these instruments to accrue income over the term of their investment. It also asks for comments on a number of related topics, including the character of income or loss with

respect to these instruments; whether short-term instruments should be subject to any such accrual regime; the relevance of factors such as the exchange-traded status of the instruments and the nature of the underlying property to which the instruments are linked; and whether these instruments are or should be subject to the constructive ownership regime, which very generally can operate to recharacterize certain long-term capital gain as ordinary income and impose a notional interest charge. While the notice requests comments on appropriate transition rules and effective dates, any Treasury regulations or other guidance promulgated after consideration of these issues could materially and adversely affect the tax consequences of an investment in the securities, possibly with retroactive effect. You should consult your tax adviser regarding the possible alternative treatments of an investment in the securities and the issues presented by this notice.

**Tax Consequences to Non-U.S. Holders**

This section applies only to non-U.S. holders. You are a non-U.S. holder if you are a beneficial owner of a security that is, for U.S. federal income tax purposes:

- an individual who is classified as a nonresident alien;
- a foreign corporation; or
- a foreign estate or trust.

You are not a non-U.S. holder for purposes of this discussion if you are (i) an individual who is present in the United States for 183 days or more in the taxable year of disposition or (ii) a former citizen or resident of the United States. If you are or may become such a person during the period in which you hold a security, you should consult your tax adviser regarding the U.S. federal tax consequences of an investment in the securities.

*Sale, Exchange or Retirement of the Securities*. Subject to the possible application of Section 897 of the Code, you generally should not be subject to U.S. federal income or withholding tax in respect of amounts paid to you, provided that income in respect of the securities is not effectively connected with your conduct of a trade or business in the United States.

If you are engaged in a U.S. trade or business, and if income from the securities is effectively connected with the conduct of that trade or business, you generally will be subject to regular U.S. federal income tax with respect to that income in the same manner as if you were a U.S. holder, unless an applicable income tax treaty provides otherwise. If you are such a holder and you are a corporation, you should also consider the potential application of a 30% (or lower treaty rate) branch profits tax.

*Tax Consequences Under Possible Alternative Treatments*. If all or any portion of a security were recharacterized as a debt instrument, subject to the possible application of Section 897 of the Code and the discussion below regarding FATCA, any payment made to you with respect to the security generally should not be subject to U.S. federal withholding or income tax, provided that: (i) income or gain in respect of the security is not effectively connected with your conduct of a trade or business in the United States, and (ii) you provide an appropriate IRS Form W-8 certifying under penalties of perjury that you are not a United States person.

Other U.S. federal income tax treatments of the securities are also possible. In 2007, the U.S. Treasury Department and the IRS released a notice requesting comments on the U.S. federal income tax treatment of prepaid forward contracts and similar instruments. Among the issues addressed in the notice is the degree, if any, to which income

with respect to instruments such as the securities should be subject to U.S. withholding tax. While the notice requests comments on appropriate transition rules and effective dates, it is possible that any Treasury regulations or other guidance promulgated after consideration of these issues might materially and adversely affect the withholding tax consequences of an investment in the securities, possibly with retroactive effect. If withholding applies to the securities, we will not be required to pay any additional amounts with respect to amounts withheld. Accordingly, you should consult your tax adviser regarding the issues presented by the notice.

***U.S. Federal Estate Tax***

If you are an individual non-U.S. holder or an entity the property of which is potentially includible in such an individual s gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), you should note that, absent an applicable treaty exemption, the securities may be treated as U.S. situs property subject to U.S. federal estate tax. If you are such an individual or entity, you should consult your tax adviser regarding the U.S. federal estate tax consequences of investing in the securities.

**Information Reporting and Backup Withholding**

Amounts paid on the securities, and the proceeds of a sale, exchange or other disposition of the securities, may be subject to information reporting and, if you fail to provide certain identifying information (such as an accurate taxpayer identification number if you are a U.S. holder) or meet certain other conditions, may also be subject to backup withholding at the rate specified in the Code. If you are a non-U.S. holder that provides an appropriate IRS Form W-8, you will generally establish an exemption from backup withholding. Amounts withheld under the backup withholding rules are not additional taxes and may be refunded or credited against your U.S. federal income tax liability, provided the relevant information is timely furnished to the IRS.

**FATCA Legislation**

Legislation commonly referred to as FATCA generally imposes a withholding tax of 30% on payments to certain non-U.S. entities (including financial intermediaries) with respect to certain financial instruments, unless various U.S. information reporting and due diligence requirements have been satisfied. An intergovernmental agreement between the United States and the non-U.S. entity s jurisdiction may modify these requirements. This legislation applies to certain financial instruments that are treated as paying U.S.-source interest or other U.S.-source fixed or determinable annual or periodical income ( FDAP income ). If required under FATCA, withholding applies to payments of interest and other FDAP income and, after 2018, to payments of gross proceeds of the disposition (including upon retirement) of certain financial instruments treated as providing U.S.-source interest or dividends. If the securities were treated as debt instruments, the withholding regime under FATCA would apply to the securities. If withholding applies to the securities, we will not be required to pay any additional amounts with respect to amounts withheld. If you are a non-U.S. holder, or a U.S. holder holding securities through a non-U.S. intermediary, you should consult your tax adviser regarding the potential application of FATCA to the securities.

**The preceding discussion constitutes the full opinion of Davis Polk & Wardwell LLP regarding the material U.S. federal tax consequences of owning and disposing of the securities.**

**You should consult your tax adviser regarding all aspects of the U.S. federal income and estate tax consequences of an investment in the securities and any tax consequences arising under the laws of any state, local or non-U.S. taxing jurisdiction.**