WATSON PHARMACEUTICALS INC
Form 10-K
February 23, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008
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 001-13305

WATSON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**95-3872914**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

311 Bonnie Circle, Corona, CA 92880 - 2882
(Address of principal executive offices, including ZIP code)

(951) 493-5300
(Registrant s telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.0033 par value	New York Stock Exchange

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

Aggregate market value of Common Stock held by non-affiliates of the Registrant, as of June 30, 2008:
$2,836,945,000 based on the last reported sales price on the New York Stock Exchange

Number of shares of Registrant s Common Stock outstanding on February 18, 2009: 104,627,327

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant s proxy statement for the 2009 Annual Meeting of Stockholders, to be held on May 8, 2009. Such proxy statement will be filed no later than 120 days after the close of the registrant s fiscal year ended December 31, 2008.

WATSON PHARMACEUTICALS, INC.

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PART I

ITEM 1. *BUSINESS*

Business Overview

Watson Pharmaceuticals, Inc. (Watson , the Company , we , us or our) is a leading specialty pharmaceutical comp engaged in the development, manufacturing, marketing, sale and distribution of generic (off-patent) and brand pharmaceutical products. Our operations are based predominantly in the United States of America (U.S.) and India, with our key commercial market being the U.S. As of December 31, 2008, we marketed approximately 150 generic pharmaceutical product families and 27 brand pharmaceutical product families through our Generic and Brand Divisions, respectively, and distributed approximately 8,000 stock-keeping units (SKUs) through our Distribution Division.

Our principal executive offices are located at 311 Bonnie Circle, Corona, California, 92880. Our Internet website address is www.watson.com. We do not intend this website address to be an active link or to otherwise incorporate by reference the contents of the website into this report. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and all amendments thereto are available free of charge on our Internet website. These reports are posted on our website as soon as reasonably practicable after such reports are electronically filed with the U.S. Securities and Exchange Commission (SEC). The public may read and copy any materials that we file with the SEC at the SEC s Public Reference Room or electronically through the SEC website (www.sec.gov). Within the Investors section of our website, we provide information concerning corporate governance, including our Corporate Governance Guidelines, Board Committee Charters and Composition, Code of Conduct and other information.

Business Description

Prescription pharmaceutical products in the U.S. generally are marketed as either generic or brand pharmaceuticals. Generic pharmaceutical products are bioequivalents of their respective brand products and provide a cost-efficient alternative to brand products. Brand pharmaceutical products are marketed under brand names through programs that are designed to generate physician and consumer loyalty. Through our Distribution Division, we distribute pharmaceutical products, primarily generics, which have been commercialized by us and others, to independent and chain pharmacies and physicians offices. As a result of the differences between the types of products we market and/or distribute and the methods we distribute products, we operate and manage our business as three operating segments: Generic, Brand and Distribution.

Business Strategy

We apply three key strategies to grow our Generic and Brand pharmaceutical businesses: (i) internal development of differentiated and high demand products, (ii) establishment of strategic alliances and collaborations and (iii) acquisition of products and companies that complement our existing portfolio. We believe that our three-pronged strategy will allow us to expand both our brand and generic product offerings. Our Distribution Division distributes products for over 200 suppliers and is focused on providing next-day delivery and responsive service to its customers. Our Distribution Division also distributes a number of Watson generic and brand products. During 2008, the Distribution Division had 12 substantial new product launches.

Based upon business conditions, our financial strength and other factors, we regularly reexamine our business strategies and may change them at anytime. See Item 1A. Risk Factors Risks Related to Our Business in this annual report on Form 10-K (Annual Report).

Generic Segment

Watson is a leader in the development, manufacturing and sale of generic pharmaceutical products. When patents or other regulatory exclusivity no longer protect a brand product, opportunities exist to introduce off-patent or generic counterparts to the brand product. These generic products are bioequivalent to their brand name counterparts and are generally sold at significantly lower prices than the brand product. As such, generic

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pharmaceuticals provide an effective and cost-efficient alternative to brand products. Our portfolio of generic products includes products we have developed internally, products we have licensed from third parties and products we distribute for third parties.

Net revenues in our Generic segment accounted for $1.47 billion or approximately 58% of our total net revenues in 2008.

Generic Strategy

Our Generic business is currently focused on maintaining a leading position within the U.S. generics market by offering a consistent and reliable supply of quality generic products. Our strategy is to develop generic pharmaceuticals that are difficult to formulate or manufacture or will complement or broaden our existing product lines. Since the prices and unit volumes of our brand products will likely decrease upon the introduction of generic alternatives, we also intend to market generic alternatives to our brand products where market conditions and the competitive environment justify such activities. Additionally, we may distribute generic versions of third parties brand products (sometimes known as Authorized Generics) to the extent such arrangements are complementary to our core business.

We have maintained an ongoing effort to enhance efficiencies and reduce costs in our manufacturing operations. Execution of these initiatives will allow us to maintain competitive pricing on our products. We are also looking to leverage our broad product line by expanding our selling and marketing presence outside the U.S. We believe a broader sales and marketing presence will allow us to expand our revenue base and minimize risk. Additionally, we are looking to establish capabilities in developing generic biologics through strategic collaborations or acquisitions.

Our portfolio of approximately 150 Generic pharmaceutical product families includes the following products, which represented 60% of total Generic segment net revenues in 2008:

Watson Generic Product	Comparable Brand Name	Therapeutic Classification
Alendronate Sodium	Fosamax®	Osteoporosis preparation
Bupropion hydrochloride SR	Zyban®	Aid to smoking cessation
Bupropion hydrochloride SR	Wellbutrin SR®	Anti-depressant
Bupropion hydrochloride XL	Wellbutrin XL®	Anti-depressant
Cartia XT®	Cardizem® CD	Anti-hypertensive
Clarithromycin ER	Biaxin® XL	Anti-biotic
Dronabinol	Marinol®	Antiemetic
Fentanyl transdermal system	Duragesic®	Analgesic/narcotic combination
Glipizide ER	Glucotrol® XL	Anti-diabetic
Hydrocodone bitartrate/ acetaminophen	Lorcet®, Vicodin®, Lortab®, Norco®/Anexia	Analgesic
Levora®	Nordette®	Oral contraceptive
Low-Ogestrel®	Lo-Ovral®	Oral contraceptive
Lutera®	Alesse®	Oral contraceptive
Microgestin®/Microgestin® Fe	Loestrin®/Loestrin® Fe	Oral contraceptive
Necon®	Ortho-Novum®, Modicon®	Oral contraceptive
Nicotine polacrilex gum	Nicorette®	Aid to smoking cessation
Omeprazole DR	Prilosec®	Gastrointestinal agent
Oxycodone/acetaminophen	Percocet®	Analgesic

TriNessa™	Ortho Tri-Cyclen®	Oral contraceptive
Trivora®	Triphasil®	Oral contraceptive

Our Generic Division also receives other revenues consisting primarily of royalties and commission revenue. During 2008, we received royalties on GlaxoSmithKline s sales of Wellbutrin XL® 150mg and received royalties on sales by Sandoz Pharmaceutical Corporation (Sandoz), a subsidiary of Novartis AG, of metoprolol succinate 50 mg extended release tablets. Additionally, we promote fentanyl citrate troche on

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behalf of Cephalon, Inc. (Cephalon) and receive commission revenue based on Cephalon s sales. During 2008, we also received a $15.0 million milestone obligation for a 1999 Schein Pharmaceutical, Inc. (Schein) litigation settlement with Barr Pharmaceuticals, Inc. (Barr) related to Cenestin. Other revenue totaled $70.4 million for 2008 or 4.8% of our total Generic segment net revenue.

We predominantly market our generic products to various drug wholesalers, mail order, government and national retail drug and food store chains utilizing 27 sales and marketing professionals. We sell our generic prescription products primarily under the Watson Laboratories and Watson Pharma labels, with the exception of our over-the-counter generic products which we sell under our Rugby® label or under private label.

During 2008, we expanded our generic product line with the launch of 11 generic products. Key launches in 2008 included bupropion hydrochloride XL 150mg tablets, an anti-depressant launched in November 2008; omeprazole 40mg delayed-release capsules, indicated for short-term treatment of active duodenal ulcer, launched in July 2008; dronabinol, indicated to treat nausea and vomiting associated with cancer chemotherapy, launched in June 2008; clarithomycin extended-release tablets, USP in the 500mg strength, an anti-infective launched in January 2008 and galantamine hydrobromide extended-release, indicated for the treatment of Alzheimer s disease, launched in December 2008.

We continue to make progress on our Global Supply Chain Initiative and the transfer of product manufacturing from our New York facility to our Florida, California, and India sites. By the end of 2009, we anticipate one-third of our manufactured volume will be produced from our Goa, India facility. By the end of 2010, we plan to close our New York solid dosage manufacturing and warehouse facilities. Additionally, we continue to implement operational efficiency programs at our manufacturing sites.

Generic Research and Development

During 2008, we took measures to enhance our pipeline of generic products by discontinuing the development of certain products and adding new products to our pipeline. At December 31, 2008, we had approximately 60 Abbreviated New Drug Applications (ANDAs) on file. See the Government Regulation and Regulatory Matters section below for a description of our process for obtaining U.S. Food and Drug Administration (FDA) approval for our products. See also Item 1A. Risk Factors Risks Related to our Business Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities. in this Annual Report.

We devote significant resources to the research and development (R&D) of generic products and proprietary drug delivery technologies. We incurred Generic segment R&D expenses of $119 million in 2008, $102 million in 2007 and $84 million in 2006. We are presently developing a number of generic products through a combination of internal and collaborative programs.

Our Generic R&D strategy focuses on the following product development areas:

- off-patent drugs that are difficult to develop or manufacture, or that complement or broaden our existing product lines;
- the development of sustained-release and other drug delivery technologies and the application of these technologies to existing drug forms; and
- using in-house technologies to develop new products.

As of December 31, 2008, we conducted R&D in Corona, California; Davie and Weston, Florida; Copiague, New York; Salt Lake City, Utah; Changzhou City, People s Republic of China; and Ambernath and Mumbai, India.

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Generic Business Development

In December 2008, we acquired a portfolio of generic pharmaceutical products that were divested as a result of the merger between Teva Pharmaceutical Industries, Ltd. (Teva) and Barr. The portfolio consists of 17 products, including 15 FDA-approved products and 2 development-stage products. Key products in the portfolio include cyclosporine capsules and liquid, desmopressin acetate tablets, glipizide/metformin HCI tablets, mirtazapine orally disintegrating tablets and metoclopramide HCI tablets. We acquired the portfolio of existing approved products for an upfront payment of $36.0 million and will make additional payments to Teva if certain milestones are met on the development-stage products. Teva has agreed to supply the products to Watson until manufacturing is transferred to Watson or a third party.

Brand Segment

Newly developed pharmaceutical products normally are patented and, as a result, are generally offered by a single provider when first introduced to the market. We currently market a number of branded products to physicians, hospitals, and other markets that we serve. We classify these patented and off-patent trademarked products as our brand pharmaceutical products. Net revenues in our Brand segment accounted for $455.0 million or approximately 18% of our total net revenues in 2008. Typically, our brand products realize higher profit margins than our generic products.

Our portfolio of 27 Brand pharmaceutical product families includes the following products, which represented 76% of total Brand segment net revenues in 2008:

Watson Brand Product	Active Ingredient	Therapeutic Classification
Androderm®	Testosterone (transdermal patch)	Male hormone replacement
Ferrlecit®	Sodium ferric gluconate in sucrose injection	Hematinic
INFeD®	Iron dextran	Hematinic
Oxytrol®	Oxybutnin (transdermal patch)	Overactive bladder
Trelstar® DEPOT	Triptorelin pamoate injection	Prostate cancer
Trelstar® LA	Triptorelin pamoate injection	Prostate cancer

We market our brand products through approximately 380 sales professionals within our specialized sales and marketing groups. Each of our sales and marketing groups focuses on physicians who specialize in the diagnosis and treatment of particular medical conditions and each group offers products to satisfy the unique needs of these physicians. We believe this focused sales and marketing approach enables us to foster close professional relationships with specialty physicians, as well as cover the primary care physicians who also prescribe in selected therapeutic areas. We generally sell our brand products under the Watson Pharma and the Oclassen® Dermatologics labels.

Our sales and marketing groups have targeted selected specialty therapeutic areas predominately because of their potential growth opportunities and the size of the physician audience. We believe that the nature of these markets and the identifiable base of physician prescribers provide us with opportunities to achieve significant market penetration through our specialized sales forces. We intend to continue to expand our brand product portfolio through internal product development, strategic alliances and acquisitions.

Our Brand segment also receives other revenues consisting of co-promotion revenue and royalties. We promote AndroGel® on behalf of Unimed Pharmaceuticals, Inc., a wholly owned subsidiary of Solvay Pharmaceuticals, Inc.

(Solvay) and other selected products on behalf of third parties. We also record revenue (including the amortization of deferred revenue) relating to our obligation to manufacture and supply Fortamet® and Altoprev® to Sciele Pharma, Inc. (Sciele), a wholly-owned subsidiary of Shionogi & Co., Ltd. Other revenue totaled $58.0 million for 2008 or 12.7% of our total Brand segment net revenue.

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Specialty Products

Our Specialty Products product line focuses on products that we market to urologists, gynecologists and targeted primary care physicians. We actively promote Oxytrol®, Trelstar Depot® and Trelstar® LA (collectively Trelstar®) through this group. We also promote AndroGel® on behalf of Solvay through this group and, in March 2009, we plan to begin co-promoting Femring®, a product for hormone replacement therapy, on behalf of Warner Chilcott Ltd.

In May 2008, we launched Mixject™, a new delivery system for Trelstar® which offers new features that makes preparation, administration and disposal of Trelstar® easier.

In April 2009, we plan to launch Rapaflo™ (silodosin), our selective alpha-blocker for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

In the second quarter of 2009, we plan to launch Gelnique™ (oxybutynin chloride gel) 10%, our topical gel for the treatment of overactive bladder.

Nephrology

Our Nephrology product line consists of products for the treatment of iron deficiency anemia. Our primary products in the Nephrology group are Ferrlecit® and INFeD®, which are indicated for patients undergoing hemodialysis in conjunction with erythropoietin therapy. Regulatory exclusivity on Ferrlecit® ended in August 2004. Additionally, we are currently engaged in an expedited arbitration proceeding to resolve a dispute with Sanofi Aventis concerning, among other things, the expiration date of our rights to market and sell Ferrlecit®. See Item 1A. Risk Factors Risks Related to our Business Loss of revenues from Ferrlecit®, a significant product, could have a material adverse effect on our results of operations, financial condition and cash flows. in this Annual Report. Also refer to *Legal Matters* in NOTE 15 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

Brand Research and Development

We devote significant resources to the R&D of brand products and proprietary drug delivery technologies. A number of our brand products are protected by patents and have enjoyed market exclusivity for 5 to 10 years and sometimes even longer. We incurred Brand segment R&D expenses of $51 million in 2008, $42 million in 2007 and $47 million in 2006.

Our Brand R&D strategy focuses on the following product development areas:

- the application of proprietary drug-delivery technology for new product development in specialty areas; and
- the acquisition of mid-to-late development-stage brand drugs.

We are presently developing a number of brand products, some of which utilize novel drug-delivery systems, through a combination of internal and collaborative programs.

During 2008 we filed a New Drug Application (NDA) with the FDA for Rapaflo™, our new alpha-blocker for the treatment of the signs and symptoms of BPH. In October 2008, our NDA was approved and we plan to launch Rapaflo™ in April 2009.

We also filed an NDA for Gelnique™, a topical gel for the treatment of overactive bladder which we believe may provide greater patient acceptance and compliance than current therapies. In January 2009 we received approval of our NDA and we anticipate launching Gelnique™ in the second quarter of 2009. Additional products in the brand pipeline include a six month formulation of Trelstar®, Uracyst, for the treatment of cystitis and a novel oral contraceptive, for the preventation of pregnancy.

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Brand Business Development

In July 2008, Mylan Inc. acquired Watson s 50% joint venture interest in Somerset Pharmaceuticals, Inc. (Somerset). Somerset developed Emsam®, a transdermal patch for the treatment of major depressive disorder, currently marketed in the United States by Bristol-Myers Squibb.

In early 2009, we entered into agreements with Warner Chilcott, Ltd. for our Specialty Products sales force to promote Femring® to gynecologists in the U.S. We also licensed an oral contraceptive from Warner Chilcott Ltd. that is currently in late stage development.

Distribution Segment

Our Distribution business, which consists of our Anda, Anda Pharmaceuticals and Valmed (also known as VIP) subsidiaries (collectively Anda), primarily distributes generic and selected brand pharmaceutical products to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains and physicians offices. Additionally, we sell to members of buying groups, which are independent pharmacies that band together to enhance their buying power. We believe that we are able to effectively compete in the distribution market, and therefore optimize our market share, based on three critical elements: (i) competitive pricing, (ii) responsive customer service that includes, among other things, next day delivery to the entire U.S. and high levels of inventory for approximately 8,000 SKUs, and (iii) well established telemarketing relationships with our customers, supplemented by our electronic ordering capabilities. While we purchase most of the approximate 8,000 SKUs in our Distribution operations from third party manufacturers, we also utilize these operations for the sale and marketing of our own products, and our collaborative partners products. We are the only U.S. pharmaceutical company that has meaningful distribution operations with direct access to independent pharmacies and we believe that our Distribution operation is a strategic asset in the national distribution of generic and brand pharmaceuticals.

Revenue growth in our Distribution operations will primarily be dependent on the launch of new products, offset by the overall level of net price and unit declines on existing distributed products and will be subject to changes in market share.

In our Distribution operations, we presently distribute products from our facilities in Weston, Florida and Groveport, Ohio. For the year ended December 31, 2008, approximately 60% of our Distribution sales were shipped from our Groveport, Ohio facility and 40% from our Weston, Florida facility, though this percentage can vary. While our Weston, Florida facility is operating at 80% capacity, our 355,000 square foot Ohio distribution center currently operates at approximately 30% capacity, and provides us with additional distribution capacity for the foreseeable future.

Strategic Alliances and Collaborations

Through collaborative agreements and strategic alliances, we develop and manufacture products that are marketed by other pharmaceutical companies, including products that utilize our patented technologies and formulation capabilities. Pursuant to a manufacturing and supply agreement and a license agreement, we supply Fortamet® and Altoprev® to Sciele.

We have a generic product development alliance with Cipla Ltd. (Cipla), the second largest pharmaceutical company in India. Under the terms of the agreement announced in December 2002, we share development responsibilities. Watson is responsible for conducting bioequivalence studies, pursuing regulatory approvals for all developed products and has exclusive U.S. marketing rights for the products. Cipla is responsible for manufacturing products.

In 2004, we entered into an exclusive licensing agreement with Kissei Pharmaceutical Co., Ltd. (Kissei) to develop and market Rapaflo™ for the North American market. The compound was originally developed and launched by Kissei in Japan as Urief® and is marketed in Japan in cooperation with Daiichi Sankyo Pharmaceutical Co., Ltd. for the treatment of the signs and symptoms of BPH.

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In October 2006, we entered into an agreement with Solvay to utilize Watson s Specialty Products sales force to co-promote AndroGel® to urologists in the U.S.

Through a R&D and supply agreement with Takeda Chemical Industries, Ltd. (Takeda), we provide contract R&D and manufacturing services to develop a combination product consisting of Takeda s Actos® (pioglitazone) and our extended-release metformin, which is administered once a day for the treatment of Type 2 diabetes. We are responsible for the formulation and manufacture of this combination product and Takeda is responsible for obtaining regulatory approval of and marketing this combination product, both in the U.S. and in other countries. Takeda submitted an NDA in 2006.

Financial Information About Segments

Watson evaluates the performance of its Generic, Brand and Distribution business segments based on net revenues, gross profit and net contribution. Summarized net revenues, gross profit and contribution information for each of the last three fiscal years, where applicable, is presented in NOTE 12 Operating Segments in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

Customers

In our Generic and Brand operations, we sell our generic and brand pharmaceutical products primarily to drug wholesalers, retailers and distributors, including national retail drug and food store chains, hospitals, clinics, mail order, government agencies and managed healthcare providers such as health maintenance organizations and other institutions. In our Distribution business, we distribute generic and certain select brand pharmaceutical products to independent pharmacies, members of buying groups, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains and physicians offices.

Sales to certain of our customers accounted for 10% or more of our annual net revenues during the past three years. The following table illustrates those customers and the respective percentage of our net revenues for which they account:

Customer	2008	2007	2006
McKesson Corporation	11%	12%	17%
Walgreen Co.	11%	11%	8%
AmeriSourceBergen Corp.	9%	9%	13%

Certain of these customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. In recent years, this distribution network has undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and large retail drug store chains. As a result, a small number of large, wholesale distributors and large chain drug stores control a significant share of the market. We expect that consolidation of drug wholesalers and retailers may adversely impact pricing and create other competitive pressures on drug manufacturers. Our Distribution business competes directly with our large wholesaler customers with respect to the distribution of generic products.

The loss of any of these customers could have a material adverse effect on our business, results of operations, financial condition and cash flows. See Item 1A. Risk Factors Risk Relating to Investing in the Pharmaceutical Industry in this Annual Report.

Competition

The pharmaceutical industry is highly competitive. In our Generic and Brand product operations, we compete with different companies depending upon product categories, and within each product category, upon dosage strengths and drug delivery systems. Such competitors include the major brand name and generic manufacturers of pharmaceutical products. In addition to product development, other competitive factors in the pharmaceutical industry include product quality and price, reputation and service and access to proprietary and technical information. It is possible that developments by others will make our products or technologies noncompetitive or obsolete.

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Competing in the brand product business requires us to identify and bring to market new products embodying technological innovations. Successful marketing of brand products depends primarily on the ability to communicate their effectiveness, safety and value to healthcare professionals in private practice, group practices and managed care organizations. We anticipate that our brand product offerings will support our existing areas of therapeutic focus. Based upon business conditions and other factors, we regularly reevaluate our business strategies and may from time to time reallocate our resources from one therapeutic area to another, withdraw from a therapeutic area or add an additional therapeutic area in order to maximize our overall growth opportunities. Our competitors in brand products include major brand name manufacturers of pharmaceuticals. Based on total assets, annual revenues and market capitalization, our Brand segment is considerably smaller than many of these competitors and other national competitors in the brand product area. Many of our competitors have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a meaningful share of those markets.

We actively compete in the generic pharmaceutical industry. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents and regulatory exclusivity for brand name products expire or are successfully challenged, the first off-patent manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products, market share, revenues and gross profit typically declines, in some cases dramatically. Accordingly, the level of market share, revenues and gross profit attributable to a particular generic product normally is related to the number of competitors in that product s market and the timing of that product s regulatory approval and launch, in relation to competing approvals and launches. Consequently, we must continue to develop and introduce new products in a timely and cost-effective manner to maintain our revenues and gross profit. In addition to competition from other generic drug manufacturers, we face competition from brand name companies in the generic market. Many of these companies seek to participate in sales of generic products by, among other things, collaborating with other generic pharmaceutical companies or by marketing their own generic equivalent to their brand products as Authorized Generics. Our major competitors in generic products include Teva Pharmaceutical Industries, Ltd., Mylan Inc., Mallinckrodt Pharmaceuticals Generics (a subsidiary of Covidien AG) and Sandoz. See Item 1A. Risk Factors Risks Related to Our Business The pharmaceutical industry is highly competitive. in this Annual Report.

In our Distribution business, we compete with a number of large wholesalers and other distributors of pharmaceuticals, including McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which distribute both brand and generic pharmaceutical products to their customers. These same companies are significant customers of our Generic and Brand pharmaceutical businesses. As generic products generally have higher gross margins than brand products for a pharmaceutical distribution business, each of the large wholesalers, on an increasing basis, are offering pricing incentives on brand products if the customers purchase a large portion of their generic pharmaceutical products from the primary wholesaler. As we do not offer a broad portfolio of brand products to our customers, we are at times competitively disadvantaged and must compete with these wholesalers based upon our very competitive pricing for generic products, greater service levels and our well-established telemarketing relationships with our customers, supplemented by our electronic ordering capabilities. Additionally, generic manufacturers are increasingly marketing their products directly to smaller chains and thus increasingly bypassing wholesalers and distributors. Increased competition in the generic industry as a whole may result in increased price erosion in the pursuit of market share.

Manufacturing, Suppliers and Materials

During 2008, we manufactured many of our own finished products at our plants in Corona, California; Davie, Florida; Goa, India; Carmel, New York; Copiague, New York and Salt Lake City, Utah. As part of an ongoing effort to

optimize our manufacturing operations, we implemented several cost reduction initiatives in 2008, which included the transfer of several solid dosage products from our Carmel, New York facility to our

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Goa, India facility, and the ongoing implementation of our operational excellence program at certain of our U.S. manufacturing facilities.

We have development and manufacturing capabilities for raw material and active pharmaceutical ingredients (API) and intermediate ingredients to support our internal product development efforts in our Goa and Ambernath, India and Changzhou, China facilities. Our Ambernath, India facility also develops and manufactures API for third parties. We also have an equity investment in Scinopharm Taiwan, Ltd., a company that specializes in the development and manufacture of API.

Our manufacturing operations are subject to extensive regulatory oversight and could be interrupted at any time. Our Corona, California facility is currently subject to a consent decree of permanent injunction. See Item 1A. Risk Factors Risks Related to Our Business Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities. Also refer to *Legal Matters* in NOTE 15 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

We contract with third parties for the manufacture of certain of our products, some of which are currently available only from sole or limited suppliers. These third-party manufactured products include products that have historically accounted for a significant portion of our revenues, such as Ferrlecit ®, bupropion hydrochloride sustained-release tablets and a number of our oral contraceptive products. Third-party manufactured products accounted for approximately 58%, 57% and 58% of our product net revenues in 2008, 2007 and 2006, respectively, and 56%, 56% and 64% of our gross profit in 2008, 2007 and 2006, respectively.

We are dependent on third parties for the supply of the raw materials necessary to develop and manufacture our products, including the API and inactive pharmaceutical ingredients used in our products. We are required to identify the supplier(s) of all the raw materials for our products in the drug applications that we file with the FDA. If raw materials for a particular product become unavailable from an approved supplier specified in a drug application, we would be required to qualify a substitute supplier with the FDA, which would likely interrupt manufacturing of the affected product. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some raw materials are available only from a single source and, in some of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist.

In addition, we obtain a significant portion of our raw materials from foreign suppliers. Arrangements with international raw material suppliers are subject to, among other things, FDA regulation, customs clearance, various import duties, foreign currency risk and other government clearances. Acts of governments outside the U.S. may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, any changes in patent laws in jurisdictions outside the U.S. may make it increasingly difficult to obtain raw materials for R&D prior to the expiration of the applicable U.S. or foreign patents. See Item 1A. Risk Factors Risks Related to Our Business If we are unable to obtain sufficient supplies from key suppliers that in some cases may be the only source of finished products or raw materials, our ability to deliver our products to the market may be impeded. in this Annual Report.

Patents and Proprietary Rights

We believe patent protection of our proprietary products is important to our Brand business. Our success with our brand products will depend, in part, on our ability to obtain, and successfully defend if challenged, patent or other proprietary protection for such products. We currently have a number of U.S. and foreign patents issued or pending. However, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. Accordingly, our patents may not prevent other companies from developing similar or functionally equivalent

products or from successfully challenging the validity of our patents. If our patent applications are not approved or, even if approved, if such patents are circumvented or not upheld in a court of law, our ability to competitively market our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to commercially market these products may be diminished. From time to time, we may need to obtain licenses to

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patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market such products may be inhibited or prevented.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our partners, customers, employees and consultants. It is possible that these agreements will be breached or will not be enforceable in every instance, and we will not have adequate remedies for any such breach. It is also possible that our trade secrets will otherwise become known or independently developed by competitors.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation concerning patents, trademarks, copyrights and proprietary technologies can often be protracted and expensive and, as with litigation generally, the outcome is inherently uncertain.

Pharmaceutical companies with brand products are increasingly suing companies that produce off-patent forms of their brand name products for alleged patent infringement or other violations of intellectual property rights which may delay or prevent the entry of such a generic product into the market. For instance, when we file an ANDA seeking approval of a generic equivalent to a brand drug, we may certify under the Drug Price Competition and Patent Restoration Act of 1984 (the Hatch-Waxman Act) to the FDA that we do not intend to market our generic drug until any patent listed by the FDA as covering the brand drug has expired, in which case, the ANDA will be approved by the FDA no earlier than the expiration or final finding of invalidity of such patent(s). On the other hand, we could certify that we believe the patent or patents listed as covering the brand drug are invalid and/or will not be infringed by the manufacture, sale or use of our generic form of the brand drug. In that case, we are required to notify the brand product holder or the patent holder that such patent is invalid or is not infringed. If the patent holder sues us for patent infringement within 45 days from receipt of the notice, the FDA is then prevented from approving our ANDA for 30 months after receipt of the notice unless the lawsuit is resolved in our favor in less time or a shorter period is deemed appropriate by a court. In addition, increasingly aggressive tactics employed by brand companies to delay generic competition, including the use of Citizen Petitions and seeking changes to U.S. Pharmacopeia, have increased the risks and uncertainties regarding the timing of approval of generic products.

Litigation alleging infringement of patents, copyrights or other intellectual property rights may be costly and time consuming. See Item 1A. Risk Factors Risks Related to Our Business Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products. in this Annual Report.

Because a balanced and fair legislative and regulatory arena is critical to the pharmaceutical industry, we will continue to devote management time and financial resources on government activities. We currently maintain an office and staff a full-time government affairs function in Washington, D.C. that maintains responsibility for keeping abreast of state and federal legislative activities.

Government Regulation and Regulatory Matters

All pharmaceutical manufacturers, including Watson, are subject to extensive, complex and evolving regulation by the federal government, principally the FDA, and to a lesser extent, by the U.S. Drug Enforcement Administration (DEA), Occupational Safety and Health Administration and state government agencies, as well as by varying regulatory agencies in foreign countries where our products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products.

FDA approval is required before any dosage form of any new drug, including an off-patent equivalent of a previously approved drug, can be marketed. The process for obtaining governmental approval to manufacture and market pharmaceutical products is rigorous, time-consuming and costly, and the extent to which it may be

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affected by legislative and regulatory developments cannot be predicted. We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and shipping new products. Consequently, there is always the risk the FDA or another applicable agency will not approve our new products, or the rate, timing and cost of obtaining such approvals will adversely affect our product introduction plans or results of operations. See Item 1A. Risk Factors Risks Related to Our Business If we are unable to successfully develop or commercialize new products, our operating results will suffer. and Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities. in this Annual Report.

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. There are generally two types of applications for FDA approval that would be applicable to our new products:

NDA. We file a NDA when we seek approval for drugs with active ingredients and/or with dosage strengths, dosage forms, delivery systems or pharmacokinetic profiles that have not been previously approved by the FDA. Generally, NDAs are filed for newly developed brand products or for a new dos