

Actavis, Inc.  
Form 10-K  
February 28, 2013  
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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, 2012**

**OR**

· **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**

**ACTAVIS, INC.**

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

**Nevada**

*(State or other jurisdiction of*

*incorporation or organization)*

**Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054**

*(Address of principal executive offices, including ZIP code)*

**(862) 261-7000** *(Registrant's telephone number, including area code)*

None

*(Former name, former address, and former fiscal year if changed since last report)*

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

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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 [x] No [ ]

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

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 [x] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 [x] No [ ]

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

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 [x] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [ ]
(Do not check if a smaller reporting company)

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

Aggregate market value of Common Stock held by non-affiliates of the Registrant, as of June 30, 2012:

\$9,442,846,857 based on the last reported sales price on the New York Stock Exchange

Number of shares of Registrant's Common Stock outstanding on February 15, 2013: 127,832,241

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant's proxy statement for the 2013 Annual Meeting of Stockholders, to be held on May 10, 2013. Such proxy statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2012.

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**ACTAVIS, INC.**

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**PART I**

**ITEM 1. BUSINESS**

**Business Overview**

On October 31, 2012, Watson Pharmaceuticals, Inc. completed the acquisition of Actavis Group. Watson Pharmaceuticals, Inc. common stock was traded on the New York Stock Exchange under the symbol WPI until close of trading on January 23, 2013, at which time Watson Pharmaceuticals, Inc. changed its corporate name to Actavis, Inc. and changed its ticker symbol to ACT. Actavis, Inc. (Actavis, the Company, we, us, or our) is a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, branded generic, brand, biosimilar and over-the-counter (OTC) pharmaceutical products. We also develop and out-license generic pharmaceutical products primarily in Europe through our Medis third-party business. Following the renaming, the Company also changed the name of its three reporting segments. The Global Generics segment has become Actavis Pharma, Global Brands has become Actavis Specialty Brands, and Distribution has become Anda Distribution.

Following the acquisition of Actavis Group, the Company now has operations in more than 60 countries throughout the Americas (U.S., Canada, and Latin America), Europe (Europe, Russia, Commonwealth of Independent States (CIS), and Turkey), and MEAAP (Middle East, Africa, Australia, and Asia Pacific). The United States of America (U.S.) remains our largest commercial market and represented approximately 81% of total net revenues for 2012. As of December 31, 2012, we marketed approximately 250 generic pharmaceutical product families and over 40 brand pharmaceutical products in the U.S. and distributed approximately 11,450 stock-keeping units (SKUs) through our Anda Distribution Division.

Our principal executive offices are located at our global and U.S. headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Our international headquarters are located at Turmstrasse 24, 6300 Zug, Switzerland. Our Internet website address is www.actavis.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. See ITEM 1A. RISK FACTORS-CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS in this Annual Report on Form 10-K (Annual Report).

**Acquisitions**

***Acquisition of Uteron Pharma SA***

On January 23, 2013, the Company completed the acquisition of Belgium-based Uteron Pharma SA for \$150.0 million in cash up front, and up to \$155.0 million in potential future milestone payments. The acquisition of Uteron expands our Actavis Specialty Brands pipeline of Women's Health products including two potential near term commercial opportunities in contraception and infertility, and one novel oral contraceptive. Several additional products in earlier stages of development are also included in the acquisition. This transaction is consistent with Actavis Specialty Brands' growth strategy, which is focused on expanding our branded product portfolio globally.

***Acquisition of Actavis Group***

On October 31, 2012, Watson Pharmaceuticals, Inc. completed the acquisition of the Actavis Group. On January 24, 2013, the Company was renamed Actavis, Inc. The acquisition was consummated for a cash payment of 4.2 billion, or approximately \$5.5 billion, and potential contingent consideration payable in the form of up to

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5.5 million newly issued shares of Actavis, Inc. common stock or, under certain conditions, in cash. Actavis Group was a privately held generic pharmaceutical company specializing in the development, manufacture and sale of generic pharmaceuticals. Actavis' financial statements included in this report do not include the financial results of the Actavis Group for any of the periods or at any of the dates presented prior to November 1, 2012.

With the acquisition of Actavis Group, the Company became the third largest global generics pharmaceutical company with operations in more than 60 countries. The acquisition expanded the Company's core leadership position in modified release, solid oral dosage and transdermal products into semi-solids, liquids and injectables. The result is a broader and more diversified global product portfolio, and an expanded development pipeline. As of December 31, 2012, the combined company had more than 185 Abbreviated New Drug Applications (ANDAs) pending at the U.S. Food and Drug Administration (FDA).

***Acquisition of Ascent Pharmahealth Ltd.***

On January 24, 2012, we completed the acquisition of Ascent Pharmahealth Ltd., the Australia and Southeast Asia generic pharmaceutical business of Strides Arcolab Ltd, for AU\$376.6 million in cash, or approximately \$392.6 million including working capital adjustments. As a result of the acquisition, the Company enhanced its commercial presence in Australia and we gained a selling and marketing capability in Southeast Asia through Ascent's line of branded-generic and over-the-counter products.

***Acquisition of Specifar Pharmaceuticals***

On May 25, 2011, we completed the acquisition of Specifar Pharmaceuticals, a privately-held multinational generic pharmaceutical company for \$398.5 million, or approximately \$559.5 million in cash, including working capital adjustments. As a result of the acquisition, we enhanced our commercial presence in key European markets through Specifar's portfolio of approved products. The transaction also gave the Company a strong branded-generic commercial presence in the Greek pharmaceutical market.

**Other Business Development Activities**

Actavis completed additional business development activities to expand its Actavis Pharma and Actavis Specialty Brands development and commercial capabilities.

***Actavis Pharma Business Development***

***Generic Concerta® and Lipitor®***

The Company's two most significant products in 2012 were the authorized generic version of Concerta® (methylphenidate ER) and Lipitor® (atorvastatin), which on a combined basis comprised 20.8% of the Company's revenues. These products were sold pursuant to exclusive marketing arrangements.

Methylphenidate ER is sold pursuant to an exclusive agreements with Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI). Under the terms of the agreement, OMJPI supplies the Company with product. Actavis, Inc. launched its authorized generic of Concerta® on May 1, 2011. Under the terms of its agreement with OMJPI, the Company pays a royalty to OMJPI based on the gross profit of product revenues as defined in the agreements. During 2012, the royalty payable to OMJPI ranged from 50% to 55% of sales. This royalty includes the cost of the product supplied by OMJPI. Our royalty payable on sales of methylphenidate ER declines when a third party competitor launches a competing bioequivalent product. The change in royalty is a one-time event and is applied on a strength-by-strength basis following the launch of the first third party generic competitor. In January of 2013, a competitor launched a generic version of the 27mg strength, triggering the one time decline in royalty on this strength. Accordingly, for the 27mg strength, commencing in January 2013, the royalty payable to OMJPI will be approximately 30% of sales, which includes the cost of the product supplied by OMJPI. The royalty on the 18mg, 35mg and 54mg strengths will remain at approximately 50% until a competitive launch occurs, at which point the royalty rate will be reduced to approximately 30%. The agreement with OMJPI expires on December 31, 2014 and is subject to normal and customary early termination provisions.

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During 2011 and 2012, Atorvastatin was sold pursuant to an exclusive agreement with Pfizer, Inc. ( Pfizer ). Actavis, Inc. launched its authorized generic of Lipitor® on November 30, 2011. Due to the significant decline in the market for this product, the Company agreed to terminate this agreement effective January 1, 2013. In exchange, the Company is entitled to receive a royalty on future sales of the product by Pfizer through 2015.

### *Generic Lidoderm®*

The Company has entered into an agreement with Endo Health Solutions Inc. ( Endo ) and Teikoku Seiyaku Co., Ltd to settle all outstanding patent litigation related to the Company s generic version of Lidoderm®. The agreement allows the Company to launch its lidocaine topical patch 5% product on September 15, 2013. The license will be exclusive as to an authorized generic version of Lidoderm® until the earliest of a third party generic launch or seven and one half months after the Company s launch of its generic product. Endo will receive approximately 25% of the gross profit generated on the Company s sales of its generic version of Lidoderm® during the Company s period of exclusivity. On August 23, 2012, the FDA granted final approval of the Company s generic version of Lidoderm®.

Additionally, under the terms of the agreement, the Company s Anda Distribution business will receive and distribute branded Lidoderm® product from Endo each month during the first eight months of 2013 valued up to approximately \$96 million. The Company s availability of brand product would cease upon the launch of any generic version of Lidoderm®. The receipt of the branded product will be recorded at the time all contingencies related to the Company s ability to receive and distribute such inventory are resolved.

### *Actavis Specialty Brands Business Development*

#### *License and supply agreement with Merck for Oxytrol® OTC*

In November 2007, the Company entered into a license and supply agreement for Oxytrol® with Merck, Inc. Under terms of the agreement, Actavis will supply the Oxytrol® product to Merck and Merck will package, distribute, sell and market the product over-the-counter in the U.S. for the treatment of over active bladder in women ( OAB ). The agreement entitles Actavis to retain marketing rights for the prescription Oxytrol® product. After conducting numerous clinical trials, Merck submitted the application in March of 2012 and received FDA approval on January 25, 2013 as the first OTC product for the treatment of OAB.

#### *Amgen Collaboration*

In December 2011, we entered into a collaboration agreement with Amgen to develop and commercialize, on a worldwide basis biosimilar versions of Herceptin®, Avastin®, Rituxan/Mab Thera®, and Erbitux®. Amgen will assume primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products. The Company will contribute up to \$400.0 million in co-development costs over the course of development, including the provision of development support, and will share product development risks. In addition, we will contribute our significant expertise in the commercialization and marketing of products in highly competitive specialty and generic markets, including helping effectively manage the lifecycle of the biosimilar products. The collaboration products are expected to be sold under a joint Amgen/Actavis label. We will initially receive royalties and sales milestones from product revenues. The collaboration will not pursue biosimilars of Amgen s proprietary products.

#### *Global Licensing Agreement for Biosimilar Herceptin®*

On July 13, 2012, the Company entered into a global license agreement with Synthon, obtaining an exclusive license to its trastuzumab molecule, which is being developed as a biosimilar to Herceptin®. Actavis subsequently contributed the product to the Company s biosimilar collaboration with Amgen. Amgen and Actavis will assume all responsibility for worldwide development and commercialization of biosimilar trastuzumab, including Phase III clinical trials and global manufacturing. The agreement entitles Synthon to an initial payment and the opportunity to receive a milestone payment and royalties on net sales. Synthon will also receive compensation for transitional support activities provided under the agreement. See ITEM 1A. RISK

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**FACTORS Risks Related to our Business** Our investments in biosimilar products may not result in products that are approved by the FDA or other ex-U.S. regulatory authorities and, even if approved by such authorities, may not result in commercially successful products in this Annual Report.

### **Disposals**

#### ***Rugby OTC Business***

On October 29, 2012, the Company sold its Rugby OTC pharmaceutical products and trademarks to The Harvard Drug Group, L.L.C. ( Harvard ) for \$116.6 million. Under the terms of the agreement, Harvard acquired the Rugby trademark and all rights to market, sell and distribute OTC products and nicotine gum products sold under the Rugby trademark. The Company retains all rights to manufacture, sell and distribute all store-branded OTC and nicotine gum products, as well as other non-Rugby OTC products in its portfolio. Actavis also retains ownership of its nicotine gum ANDAs and nicotine gum manufacturing facilities. As part of the transaction, Actavis and Harvard entered into a supply and license agreement under which Actavis will manufacture and supply nicotine gum products sold in the Rugby and Major labels. Major is Harvard s existing private label brand.

#### ***Sale of Moksha8 Ownership***

On October 22, 2012, the Company sold its investment in Moksha8 for \$46.6 million. Simultaneously, the Company expanded its ongoing sales and marketing collaboration with Moksha8 by granting a license to Moksha8 for five new branded generic products to be developed for the Brazil and Mexico markets in exchange for defined milestones and sales royalties. The Company will continue to retain generic marketing rights in each market for all products licensed to Moksha8. The Company had acquired a minority ownership share in Moksha8 for cash totaling \$30.0 million in October of 2010.

### **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, or in cases of protein-based biologic therapies, biosimilar, 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 And a Distribution Segment, we distribute pharmaceutical products, primarily generics, which have been commercialized by us and others, to 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 these products, we operate and manage our business as three distinct operating segments: Actavis Pharma, Actavis Specialty Brands and And a Distribution. The Company also develops and out-licenses generic pharmaceutical products through its Medis third-party business.

### **Business Strategy**

We apply three key strategies to achieve growth for our Actavis Pharma and Actavis Specialty Brands pharmaceutical businesses: (i) internal development of differentiated and high-demand products, including, in certain circumstances, challenging patents associated with these products, (ii) establishment of strategic alliances and collaborations and (iii) acquisition of products and companies that complement our current business. We believe our three-pronged strategy will allow us to expand both our brand and generic product offerings globally. Our Medis third-party business has a broad portfolio of over 200 developed products for out licensing to approximately 300 customers, primarily in Europe. Our And a Distribution business distributes products for over 260 suppliers and is focused on providing next-day delivery and responsive service to its customers. Our And a Distribution business also distributes a number of generic and brand products in the U.S. Growth in our And a Distribution business will be largely dependent upon FDA approval of new generic products in the U.S. and expansion of our base of suppliers.

Based upon business conditions, our financial strength and other factors, we regularly reexamine our business strategies and may change them at any time. See ITEM 1A. RISK FACTORS Risks Related to Our Business in this Annual Report.

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### **Actavis Pharma Segment**

Actavis is a leader in the development, manufacturing and sale of generic, branded generic and OTC pharmaceutical products. In certain cases where patents or other regulatory exclusivity no longer protect a brand product, or other opportunities might exist, Actavis seeks to introduce 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. Our portfolio of generic products includes products we have developed internally and products licensed from and distributed for third parties. Net revenues in our Actavis Pharma segment accounted for \$4.4 billion or approximately 75.2% of our total net revenues in 2012. Our Actavis Pharma business in the U.S. remains the dominant source of revenue for the Company with approximately 75% of 2012 segment net revenue coming from our U.S. businesses. While our U.S. generics business will continue to be the dominant source of revenue for the company, we expect international generic revenue to represent an increasing percentage of total revenues in future periods due to the acquisition of Actavis Group.

### **Actavis Pharma Strategy**

Our Actavis Pharma business is focused on maintaining a leading position within both the U.S. generics market and our key international markets and strengthening our global position by offering a consistent and reliable supply of quality products.

Our strategy in the U.S. is to develop generic pharmaceuticals that are difficult to formulate or manufacture or will complement or broaden our existing product lines. Internationally, we seek to grow our market share in key markets while expanding our presence in new markets. We plan to accomplish this through new product launches, filing existing products overseas and in-licensing products through acquisitions and strategic alliances. Additionally, we 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.



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Our U.S. portfolio of approximately 250 generic pharmaceutical product families includes the following key products which represented approximately 57% of total Actavis Pharma segment product revenues in 2012:

<b>Actavis Generic Product</b>	<b>Comparable Brand Name</b>	<b>Therapeutic Classification</b>
Amethia	Seasonique®	Oral contraceptive
Atorvastatin	Lipitor®	Adjunct to reduce elevated levels of cholesterol
Bupropion hydrochloride ER	Wellbutrin XL®	Anti-depressant
Clopidogrel	Plavix®	Antiplatelet
Dronabinol	Marinol®	Antiemetic
Enoxaparin sodium	Lovenox®	Anticoagulant
Fentanyl transdermal system	Duragesic®	Analgesic/narcotic combination
Glipizide ER	Glucotrol XL®	Anti-diabetic
Hydrocodone bitartrate/ acetaminophen	Lorcet®, Lorcet® Plus, Lortab®, Norco®/Anexsia®, Maxidone®, Vicodin®, Vicodin ES®, Vicodin HP®, Xopenex® Inhalation Solution	Analgesic
Levalbuteral inhalation solution	Xopenex® Inhalation Solution	Bronchodilator
Lutera®	Alesse®	Oral contraceptive
Methylphenidate ER	Concerta®	Hypertension, attention-deficit/ hyperactivity disorder
Metformin hydrochloride	Glucophage®	Hypoglycemic
Metoprolol succinate	Toprol XL®	Anti-hypertensive
Microgestin®/Microgestin® Fe	Loestrin®/Loestrin® Fe	Oral contraceptive
Morphine sulfate	Kadian®	Analgesic
Next Choice One Dose™	Plan B One-Step®	Emergency oral contraceptive
Nicotine gum	Nicorette®	Aid to smoking cessation
Oxycodone hydrochloride / acetaminophen	Percocet®	Analgesic
Potassium	Micro-K®, K-Dur®	Hypokalemia
Progesterone	Prometrium®	Hormone
Testosterone Cypionate	Depo® Testosterone	Androgenic and anabolic steroid, antineoplastic
Testosterone Enanthate	Delatestryl®	Androgenic and anabolic steroid, antineoplastic
Trinessa®	Ortho Tri-Cyclen	Oral contraceptive
Vancomycin hydrochloride	Vancocin® HCl	Antibiotic
Zarah®	Yasmin®	Oral contraceptive

In the U.S., we predominantly market our generic products to various drug wholesalers, mail order, government and national retail drug and food store chains utilizing a small team of sales and marketing professionals. We sell our generic prescription products primarily under the Watson Laboratories, Watson Pharma and Actavis Pharma labels, and our over-the-counter generic products under private label. Following the renaming of Watson Pharmaceuticals, Inc. to Actavis, Inc. efforts are underway to change the underlying Watson subsidiary and legal entity names to an Actavis name. This process is expected to continue to roll out throughout the year.

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During 2012, on a combined business, we expanded our generic product line with the launch of over 1,000 generic products globally. Key U.S. generic launches in 2012 included enoxaparin sodium injection, progesterone, USP (an authorized generic version of Prometrium®), vancomycin hydrochloride, metformin hydrochloride extended release, ibandronate sodium, Next Choice™ (a generic version of Plan B One-Step®), trospium chloride extended release, levalbuterol hydrochloride inhalation solution, diclofenac sodium and misoprostol delayed-release, irbesartan USP, and pioglitazone hydrochloride. In addition, prior to being acquired by the Company, Actavis Group launched several key generic products in 2012, including a generic version of Adderall XR® in the U.S.

### **Operations in Key International Markets**

Approximately 25% of our Actavis Pharma revenue was derived outside the U.S. in 2012 primarily in Western Europe, Canada and Australia. As a result of the acquisition of Actavis Group on October 31, 2012, the percentage of Actavis Pharma revenue derived outside the U.S. is expected to increase. The Company now has operations in more than 60 countries, with leading generic market share positions in more than 33 markets including the U.S., U.K., Canada, Australia, Nordics and Russia.

### **Actavis Pharma Research and Development**

We devote significant resources to the research and development of generic products and proprietary drug delivery technologies. The Actavis Pharma segment incurred R&D expenses of approximately \$255.6 million in 2012, \$227.7 million in 2011, and \$194.6 million in 2010. We are presently developing a number of generic products through a combination of internal and collaborative programs.

Our Actavis Pharma 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; and

the development of sustained-release, semi-solid, liquid, oral transmucosal, transdermal, gel, injectable, and other drug delivery technologies and the application of these technologies to proprietary drug forms.

We conduct research and development through a network of 18 global R&D centers. Our R&D activities focus on products using solid dosage form, oral controlled and sustained release, transdermal, gel and oral transmucosal technologies and following the acquisition of Actavis Group, also focus on liquids, semi-solids and injectibles. As of December 31, 2012, we conducted the majority of our R&D activities in Davie and Weston, Florida; Salt Lake City, Utah; Elizabeth New Jersey; Owings Mills, Maryland; Ag. Varvara, Greece; Mumbai, India; Liverpool, UK and Mississauga, Canada.

As of December 31, 2012, we had more than 185 ANDAs on file in the U.S. See the Government Regulation and Regulatory Matters section below for a description of our process for obtaining U.S. Food and Drug Administration approval for our products. See also ITEM 1A. RISK FACTORS Risks Relating To Investing In the Pharmaceutical Industry 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.

### **Actavis Specialty Brands Segment**

Newly developed pharmaceutical products normally are patented or have market exclusivity 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. In April 2012, we launched Gelnique 3%™ (oxybutynin), a clear, odorless topical gel that has been shown to be an effective and safe treatment for OAB. Gelnique 3%™ was obtained through an exclusive licensing agreement with Antares. Net revenues in our Actavis Specialty Brands segment were \$482.4 million or approximately 8% of our total net revenues in 2012. Typically, our brand products realize higher profit margins than our generic products.

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Our portfolio of over 40 brand pharmaceutical products includes the following key products, which represented approximately 71% of total Actavis Specialty Brands segment product revenues in 2012:

<b>Actavis Brand Product</b>	<b>Active Ingredient</b>	<b>Therapeutic Classification</b>
Androderm®	Testosterone (transdermal patch)	Male testosterone replacement
Crinone®	Progesterone gel	Progesterone supplementation
Gelnique®	Oxybutnin Chloride (gel 3% and 10%)	Overactive bladder
Generess® Fe	Ethinyl estradiol and norethindrone	Oral contraceptive
INFeD®	Iron dextran	Hematinic
Oxytrol®	Oxybutnin (transdermal patch)	Overactive bladder
Rapaflo®	Silodosin	Benign prostatic hyperplasia
Trelstar®	Triptorelin pamoate injection	Prostate cancer

We market our brand products through approximately 430 sales professionals in the U.S. Our sales and marketing efforts focus on physicians, specifically urologists, obstetricians and gynecologists, who specialize in the diagnosis and treatment of particular medical conditions. Each group offers products to satisfy the unique needs of these physicians. Approximately 54 of these sales professionals are strategic account specialists who focus on institutions and clinics. 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 label. Following the renaming of Watson Pharmaceuticals, Inc. to Actavis, Inc. efforts are underway to change the underlying subsidiary and legal entities names to an Actavis name. We believe that the current structure of sales professionals is very adaptable to the additional products we plan to add to our brand portfolio, particularly in the therapeutic category of women's health.

Our key promoted products are Rapaflo®, Gelnique®, Trelstar®, Androderm®, Generess® Fe and Crinone®. Our Actavis Specialty Brands segment also receives other revenues consisting of co-promotion revenue and royalties. We promote AndroGel® on behalf of Abbvie Inc. We expect to continue this strategy of supplementing our existing brand revenues with co-promoted products within our targeted therapeutic areas. Other revenue totaled \$70.8 million for 2012 or approximately 14.7% of our total Actavis Specialty Brands segment net revenue.

**Operations in Key International Markets**

In conjunction with our strategy to grow and expand our Actavis Specialty Brands business in the Americas, in 2011 we established a commercial presence in Canada and in 2012 we began marketing and selling Rapaflo®, Gelnique® Oxytrol®, and Androderm® in Canada. Our Canadian sales efforts are supported by a sales force of approximately 24 representatives, targeting urologists and primary care physicians. Actavis plans to seek approval for several of its core Urology and Women's healthcare branded products in both Brazil and Mexico and intends to commercialize the products in this region once approval is obtained.

Outside of the Americas, we intend to maximize the value of our brand product portfolio and pipeline by utilizing the assets and expertise brought to our organization by the Actavis Group acquisition. Outside of the U.S., Actavis has a sales force of over 2,000 representatives that actively promote branded, generic, branded-generic, and OTC medicines. This sales force will play an important role in expanding the global commercial value of our branded portfolio.

**Actavis Specialty Brands Research and Development**

We devote significant resources to the R&D of brand products, biosimilars and proprietary drug delivery technologies. A number of our brand products are protected by patents and have enjoyed market exclusivity. Actavis Specialty Brands segment R&D expenses were \$146.2 million in 2012, \$67.7 million in 2011, and \$101.5 million in 2010.

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Our Actavis Specialty Brands 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 and biosimilars.

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.

Products in the brand pipeline include a second generation progesterone vaginal gel for infertility, Esmya in Canada for pre-surgical reduction of menstrual bleeding associated with uterine fibroids and in the U.S. for long-term uterine sparing, as well as two novel long-acting contraceptives in late stage development, a progestin-only patch and a vaginal ring. We also have a number of products in development as part of our life-cycle management strategy on our existing product portfolio.

With the acquisition of Uteron Pharma SA in January of 2013, we added three near-term products to our brand pipeline including Levosert® and Estelle® in contraception, Diafert® in infertility, and several additional products in earlier stages of development. Levosert® is an Intrauterine Device (IUD) for the indications of long term contraception and treatment of heavy bleeding. The product is currently pending approval in several European Union ( EU ) countries for first indication and is in late Phase III development for the U.S. market. Actavis has marketing rights for Levosert® in Western Europe and other regions and is partnered with third parties in the U.S., certain eastern European countries and certain other countries. Diafert® is a non-invasive immunoassay kit for the assessment of oocyte (egg) quality during in-vitro fertilization ( IVF ). We are currently preparing Diafert® for CE mark registration in the EU and expect to enter in Phase III development in the U.S. Estelle® is a novel oral contraceptive product being developed for global markets and is currently in late Phase II development in the U.S.

***Biosimilars***

Biosimilars development efforts are managed by our Actavis Specialty Brands segment.

In July 2010, the Company entered into an exclusive, worldwide licensing agreement with Itero Biopharmaceuticals, Inc. ( Itero ), a venture-backed specialty biopharmaceutical company, to develop and commercialize Itero s recombinant follicle stimulating hormone ( rFSH ) product. In 2012, the product began clinical development as a biosimilar molecule for the treatment of female infertility. Under the terms of the agreement, Actavis paid Itero an undisclosed licensing fee and will make additional payments based on the achievement of certain development and regulatory performance milestones. Upon successful commercialization, Actavis will also pay Itero a percentage of net sales or net profits in various regions of the world. Actavis assumed responsibility for all future development, manufacturing, and commercial expenses related to Itero s rFSH product.

In December 2011, we entered into a collaboration agreement with Amgen, Inc. ( Amgen ) to develop and commercialize, on a worldwide basis biosimilar versions of Herceptin®, Avastin®, Rituxan/Mab Thera®, and Erbitux®. Amgen will assume primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products. The Company will contribute up to \$400.0 million in co-development costs over the course of development, including the provision of development support, and will share product development risks. In addition, we will contribute our significant expertise in the commercialization and marketing of products in highly competitive specialty and generic markets, including helping effectively manage the lifecycle of the biosimilar products. The collaboration products are expected to be sold under a joint Amgen/Actavis label. We will initially receive royalties and sales milestones from product revenues. The collaboration will not pursue biosimilars of Amgen s proprietary products.

On July 13, 2012, the Company entered into a global license agreement with Synthon, obtaining an exclusive license to its trastuzumab molecule, which is being developed as a biosimilar to Herceptin®. Actavis subsequently contributed the product to the Company s biosimilar collaboration with Amgen. Amgen and Actavis will assume all responsibility for worldwide development and commercialization of biosimilar

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trastuzumab, including Phase III clinical trials and global manufacturing. The agreement entitles Synthon to an initial payment and the opportunity to receive a milestone payment and royalties on net sales. Synthon will also receive compensation for transitional support activities provided under the agreement.

### **Anda Distribution Segment**

Our Anda Distribution business primarily distributes generic and selected brand pharmaceutical products, vaccines, injectables and over-the-counter medicines 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 join 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) high levels of inventory for approximately 11,450 SKUs for responsive customer service that includes, among other things, next day delivery to the entire U.S., and (iii) well established telemarketing relationships with our customers, supplemented by our electronic ordering capabilities. While we purchase most of the approximate 11,450 SKUs in our Anda Distribution operations from third party manufacturers, we also distribute 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.

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.

We presently distribute products from our facilities in Weston, Florida, Groveport, Ohio, and Olive Branch, Mississippi as well as a small volume of product from Puerto Rico. In 2012, we completed construction of the 234,000 square foot distribution facility in Olive Branch, MS and over time, we expect to relocate our Groveport, Ohio distribution operations to this new facility.

### **Financial Information About Segments and Geographic Areas**

Actavis evaluates the performance of its Actavis Pharma, Actavis Specialty Brands and Anda Distribution business segments based on net revenues and net contribution. Summarized net revenues and contribution information for each of the last three fiscal years in the U.S. and internationally, where applicable, is presented in NOTE 14 Segments in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

### **Customers**

In our Actavis Pharma and Actavis Specialty Brands 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 Anda Distribution business, we distribute generic and certain select brand pharmaceutical products to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains, physicians' offices and buying groups.

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 any customer, on a global basis, which accounted for 10% or more of our annual net revenues and the respective percentage of our net revenues for which they account for each of the last three years:

<b>Customer</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
Walgreen Co.	16%	16%	14%
McKesson Corporation	14%	14%	11%

McKesson and certain of our other customers comprise a significant part of the distribution network for pharmaceutical products in North America. As a result, a small number of large, wholesale distributors and large

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chain drug stores control a significant share of the market. This concentration may adversely impact pricing and create other competitive pressures on drug manufacturers. Our Anda 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 Actavis Pharma and Actavis Specialty Brands businesses, 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.

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 receive formulary status from 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 Actavis Specialty Brands segment is considerably smaller than many of these competitors and other global 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 certain contracted business, such as the Pharmacy Benefit Manager business, and 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 decline, 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 include Teva Pharmaceutical Industries, Ltd., Mylan Inc. and Sandoz, Inc. (a division of Novartis AG). See ITEM 1A. RISK FACTORS Risks Relating To Investing In the Pharmaceutical Industry The pharmaceutical industry is highly competitive and our future revenue growth and profitability are dependent on our timely development and launches of new products ahead of our competitors. in this Annual Report.

In our Anda Distribution business, we compete with a number of large wholesalers and other distributors of pharmaceuticals, including McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc.,

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which distribute both brand and generic pharmaceutical products to their customers. These same companies are significant customers of our Actavis Pharma and Actavis Specialty Brands 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 majority 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 drug store chains with warehousing facilities 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. See ITEM 1A. RISK FACTORS Risks Related to Our Business Our distribution operations compete directly with significant customers of our generic and brand businesses in this Annual Report.

### **Manufacturing, Suppliers and Materials**

During 2012, we manufactured many of our own finished products at our plants including major manufacturing sites in Athens, Greece; Barnstaple, UK; Birzebugia, Malta; Corona, California; Davie, Florida; Dupnitsa, Bulgaria; Elizabeth, NJ; Goa, India; Hafnarfjordur, Iceland; Lincolnton, NC; Mississauga, Canada; and Salt Lake City, Utah. We have implemented several cost reduction initiatives, which included the transfer of several solid dosage products from our Mississauga, Canada facility to our Goa, India and Birzebugia, Malta facilities, and the ongoing implementation of our Operational Excellence Initiative at certain of our manufacturing facilities. Our manufacturing facilities also include additional plants supporting local markets and alternative dosage forms. For a full list of manufacturing facilities please refer to ITEM 2. PROPERTIES in this Annual Report.

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 Coleraine, Northern Ireland and Ambernath, India facilities. Our Ambernath, India facility also manufactures API for third parties.

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 Relating To Investing In the Pharmaceutical Industry 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 18 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

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 many of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist.

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

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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. See also ITEM 1A. RISK FACTORS Risks Relating To Investing In the Pharmaceutical Industry The supply of APIs into Europe may be negatively affected by recent regulations promulgated by the European Union in this Annual Report.

### **Patents and Proprietary Rights**

We believe patent protection of our proprietary products is important to our Actavis Specialty Brands 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 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. Patents covering our Androderm® and INFed® products have expired and we have no further patent protection on these products.

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 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 in the U.S. 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 and *Legal Matters* in NOTE 18 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.



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### **Government Regulation and Regulatory Matters**

#### *United States*

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.

All pharmaceutical manufacturers, including Actavis, 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 various 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. In our international markets, the approval, manufacture and sale of pharmaceutical products is similar to the United States with some variations dependent upon local market dynamics.

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 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. 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 Risks Relating To Investing In the Pharmaceutical Industry 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 New Drug Application ( 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 dosage form of previously approved drugs.

*ANDA.* We file an ANDA when we seek approval for off-patent, or generic equivalents of a previously approved drug. FDA approval of an ANDA is required before we may begin marketing an off-patent or generic equivalent of a drug that has been approved under an NDA, or a previously unapproved dosage form of a drug that has been approved under an NDA. The ANDA approval process generally differs from the NDA approval process in that it does not typically require new preclinical and clinical studies; instead, it relies on the clinical studies establishing safety and efficacy conducted for the previously approved NDA drug. The ANDA process, however, typically requires data to show that the ANDA drug is bioequivalent to the previously approved drug. Bioequivalence compares the bioavailability of one drug product with another and, when established, indicates whether the rate and extent of absorption of a generic drug in the body are substantially equivalent to the previously approved drug. Bioavailability establishes the rate and extent of absorption, as determined by the time dependent concentrations of a drug product in the bloodstream or body needed to produce a therapeutic effect. The ANDA drug development and approval process generally takes three to four years which is less time than the NDA drug development and approval process since the ANDA process does not require new clinical trials establishing the safety and efficacy of the drug product.

Supplemental NDAs or ANDAs are required for, among other things, approval to transfer certain products from one manufacturing site to another or to change an API supplier, and may be under review for a year or

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more. In addition, certain products may only be approved for transfer once new bioequivalency studies are conducted or other requirements are satisfied.

To obtain FDA approval of both NDAs and ANDAs, our manufacturing procedures and operations must conform to FDA quality system and control requirements generally referred to as current Good Manufacturing Practices ( cGMP ), as defined in Title 21 of the U.S. Code of Federal Regulations. These regulations encompass all aspects of the production process from receipt and qualification of components to distribution procedures for finished products. They are evolving standards; thus, we must continue to expend substantial time, money and effort in all production and quality control areas to maintain compliance. 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 the continuing possibility that we may be adversely affected by regulatory actions despite our efforts to maintain compliance with regulatory requirements.

We are subject to the periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and other authorities, which conduct periodic inspections to assess compliance with applicable regulations. In addition, in connection with its review of our applications for new products, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes comply with cGMP and other FDA regulations. Among other things, the FDA may withhold approval of NDAs, ANDAs or other product applications of a facility if deficiencies are found at that facility. Vendors that supply finished products or components to us that we use to manufacture, package and label products are subject to similar regulation and periodic inspections.

Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA investigators believe may violate cGMP or other FDA regulations. FDA guidelines specify that a Warning Letter be issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, ANDAs or other product application enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on us. See ITEM 1A. RISK FACTORS Risks Relating To Investing In the Pharmaceutical Industry 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. The Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA. Under this Act, the FDA has the authority to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and/or withdraw approval of an ANDA and seek civil penalties. The FDA can also significantly delay the approval of any pending NDA, ANDA or other regulatory submissions under the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy Act.

U.S. Government reimbursement programs include Medicare, Medicaid, TriCare, and State Pharmacy Assistance Programs established according to statute, government regulations and policy. Federal law requires that all pharmaceutical manufacturers, as a condition of having their products receive federal reimbursement under Medicaid, must pay rebates to state Medicaid programs on units of their pharmaceuticals that are dispensed to Medicaid beneficiaries. With enactment of the Affordable Care Act ( ACA ) as it is now known, the required per-unit rebate for products marketed under ANDAs increased from 11% of the average manufacturer price to 13%. Additionally, for products marketed under NDAs, the manufacturers rebate increased from 15.1% to 23.1% of the average manufacturer price, or the difference between the average manufacturer price and the lowest net sales price to a non-government customer during a specified period. In some states, supplemental rebates are required as a condition of including the manufacturer's drug on the state's Preferred Drug List.

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ACA also made substantial changes to reimbursement when seniors reach the Medicare Part D coverage gap donut hole. By 2020, Medicare beneficiaries will pay 25% of drug costs when they reach the coverage threshold the same percentage they were responsible for before they reached that threshold.

The cost of closing the donut hole is being borne by generic and brand drug companies. Beginning in 2011, brand drug manufacturers were required to provide a 50% discount on their drugs. Additionally, beginning in 2013, the government will provide subsidies for brand-name drugs bought by seniors who enter the coverage gap. The government's share will start at 2.5%, but will increase to 25% by 2020. At that point, the combined industry discounts and government subsidies will add up to 75% of brand-name drug costs. Government subsidies currently cover 7% of generic drug costs. The government will subsidize additional portions each year until 2020, when federal government subsidies will cover 75% of generic drug costs. By 2020, the donut hole will be completely closed through these manufacturers' subsidies.

The Deficit Reduction Act of 2005 (DRA) mandated a number of changes in the Medicaid program, including the use of Average Manufacturers Price (AMP) as the basis for reimbursement to pharmaceutical companies that dispense generic drugs under the Medicaid program. Three health care reform bills passed in 2010 significantly changed the definition of AMP, effective October 1, 2010. These legislative changes were part of ACA, the Health Care and Education Reconciliation Act, and the FAA Air Transportation Modernization & Safety Improvement Act (Transportation Bill). In ACA, Congress substantially revised the definition of AMP to, among other things, narrow the scope of prices included in the calculation of AMP to those paid to a manufacturer by wholesalers for drugs distributed to retail community pharmacies or by retail community pharmacies that purchase directly from manufacturers. In August 2010, Congress further amended the definition of AMP to specify that the exclusion of certain classes of trade from AMP does not apply to inhalation, infusion, instilled, implanted, or injected drugs that typically are not dispensed to retail community pharmacies. ACA also requires disclosure of weighted average AMP instead of manufacturer AMP, which was previously required. The impact of this new legislation is that there will likely be increases in Medicaid reimbursement to pharmacies for generics. These changes became effective on October 1, 2010.

On November 9, 2010, the Center for Medicare and Medicaid Services (CMS) issued a final rule withdrawing and amending regulations that have governed the calculation of AMP and the establishment of federal upper limits since October 2007. The regulations were withdrawn to mandate AMP calculation under the recently revised drug rebate statute. The withdrawal required manufacturers to base October 2010 and subsequent months' AMPs on the statutory language until official guidance is issued.

In the absence of regulatory guidance governing the AMP calculation, CMS had instructed pharmaceutical manufacturers to base their AMP calculations on the definitions set forth in the statute, as amended by the ACA, the Health Care and Education Reconciliation Act, and the Transportation Bill. Without the benefit of interpretive guidance from CMS, Watson adopted mechanisms to ensure that we were calculating and reporting AMP in a manner that was consistent with the statute's text and intent.

In subsequent months, CMS posted draft weighted average monthly AMPs and draft Federal Upper Limits in advance of publishing the new AMP rule. On January 27, 2012, CMS issued proposed rules on Medicaid pharmacy reimbursement using the AMP model. On June 28, 2012, the United States Supreme Court upheld the individual mandate provisions of ACA as a tax, and therefore, allowable under Congress' powers to levy taxes. There remain efforts in numerous states' legislatures to limit, alter or oppose the law.

To assist us in commercializing products, we have obtained from government authorities and private health insurers and other organizations, such as Health Maintenance Organizations (HMOs) and Managed Care Organizations (MCOs), authorization to receive reimbursement at varying levels for the cost of certain products and related treatments. Third party payers increasingly challenge pricing of pharmaceutical products. The trend toward managed healthcare in the U.S., the growth of organizations such as HMOs and MCOs and legislation to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. Such cost containment measures and healthcare legislation could affect our ability to sell our products and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Due to the uncertainty surrounding reimbursement of newly approved pharmaceutical products, reimbursement may not be available for

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some of our products. Additionally, any reimbursement granted may not be maintained or limits on reimbursement available from third-party payers may reduce the demand for, or negatively affect the price of, those products.

Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us. In addition, we are subject, as are all manufacturers generally, to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances and the discharge of pollutants into the air and water. Environmental permits and controls are required for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could be adversely affected by any failure to comply with environmental laws, including the costs of undertaking a clean-up at a site to which our wastes were transported.

As part of the Medicare Prescription Drug and Modernization Act of 2003 ( MMA ), companies are required to file with the U.S. Federal Trade Commission ( FTC ) and the Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of brand drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this requirement, and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, is uncertain and could adversely affect our business. For example, in January 2009, the FTC and the State of California filed a lawsuit against us alleging that our settlement with Solvay related to our ANDA for a generic version of AndroGel® is unlawful. Beginning in February 2009, several private parties purporting to represent various classes of plaintiffs filed similar lawsuits. We were successful in obtaining a dismissal of the FTC 's lawsuit, and such dismissal was affirmed by the U.S. Court of Appeals for the Eleventh Circuit. However, in December 2012 the FTC 's petition to the U.S. Supreme Court for a writ of certiorari in Federal Trade Commission v. Watson Pharmaceuticals Inc., 677 F.3d 1298 (11<sup>th</sup> Cir. 2012) was granted. Oral arguments on the petition are scheduled for March 25, 2013.

Additionally, we have received requests for information, sometimes in the form of civil investigative demands or subpoenas, from the FTC and the European Competition Commission, and are subject to ongoing FTC and European Competition Commission investigations. Two of our Arrow Group subsidiaries currently are the subject of a European Competition Commission Statement of Objection related to their 2002 and 2003 settlements of patent litigation related to citalopram. Any adverse outcome of these or other investigations or actions could have a material adverse effect on our business, results of operations, financial condition and cash flows. See ITEM 1A. RISK FACTORS Risks Relating To Investing In the Pharmaceutical Industry Federal regulation of arrangements between manufacturers of brand and generic products could adversely affect our business. Also refer to *Legal Matters* in NOTE 18 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

Our Anda Distribution operations and our customers are subject to various regulatory requirements, including requirements from the DEA, FDA, and state boards of pharmacy and city and county health regulators, among others. These include licensing, registration, recordkeeping, security and reporting requirements. For example, the DEA requires our Anda Distribution business to monitor customer orders of DEA Scheduled Drugs and to report suspicious orders to the DEA. Any determination by the DEA that we have failed to comply with applicable laws and regulations could result in DEA suspending, terminating or refusing to renew Anda Distribution 's license to distribute Scheduled Drugs. Additionally, numerous states and the federal government have begun to enforce anti-counterfeit drug pedigree laws which require the tracking of all transactions involving prescription drugs beginning with the manufacturer, through the supply chain, and down to the pharmacy or other health care provider dispensing or administering prescription drug products. For example, effective July 1, 2006, the Florida Department of Health began enforcement of the drug pedigree requirements for distribution of prescription drugs in the State of Florida. Pursuant to Florida law and regulations, wholesalers and distributors, including our subsidiary, Anda, are required to maintain records documenting the chain of custody of

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prescription drug products they distribute beginning with the purchase of such products from the manufacturer. These entities are required to provide documentation of the prior transaction(s) to their customers in Florida, including pharmacies and other health care entities. Several other states have proposed or enacted legislation to implement similar or more stringent drug pedigree requirements. In addition, federal law requires that a non-authorized distributor of record must provide a drug pedigree documenting the prior purchase of a prescription drug from the manufacturer or from an authorized distributor of record. In cases where the wholesaler or distributor selling the drug product is not deemed an authorized distributor of record, it would need to maintain such records. The FDA had announced its intent to impose additional drug pedigree requirements (e.g., tracking of lot numbers and documentation of all transactions) through implementation of drug pedigree regulations which were to have taken effect on December 1, 2006. However, a federal appeals court has issued a preliminary injunction to several wholesale distributors granting an indefinite stay of these regulations pending a challenge to the regulations by these wholesale distributors. See ITEM 1A. RISK FACTORS Risks Relating to Investing In the Pharmaceutical Industry 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.

***European Union***

Pharmaceutical regulation and marketing in Europe similar to that of U.S. requirements. Pharmaceutical manufacturers are regulated in the EU by the European Medicines Agency (EMA). All manufacturers are required to submit medicinal products, including generic versions of previously approved products and new strengths, dosages and formulations of previously approved products, to the EMA and its member states for review and marketing authorization before they are placed on the market in the EU.

Marketing authorizations are granted to sponsors after a positive assessment of quality, safety and efficacy of the product by the respective health authority. Application must contain the results pre-clinical tests, pharmaceutical tests, and clinical trials. All of these tests must have been conducted in accordance within European regulations and must allow the reviewing body to evaluate the quality, safety and efficacy of the medicinal product.

In addition to obtaining marketing authorization for each product, most member states require that a manufacturer's facilities obtain approval from the national authority. The EU has a code of good manufacturing practices that each manufacturer must follow and comply. Regulatory authorities in the EU may conduct inspections of the manufacturing facilities to review procedures, operating systems and personnel qualifications. See ITEM 1A. RISK FACTORS Risks Relating to Investing In the Pharmaceutical Industry The supply of APIs into Europe may be negatively affected by recent regulations promulgated by the European Union in this Annual Report.

In the EU, member states regulate the pricing of pharmaceutical products, and in some cases, the formulation and dosing of these products. This regulation is handled by individual member state national health services. These individual regulatory bodies can result in considerable price differences and product availability among member states. Recent efforts to implement a tendering system for the pricing of pharmaceuticals in several countries will impact drug pricing for generics; generally tendering refers to a system that requires bids to be submitted to the government by competing manufacturers to be the exclusive, or one of a few supplier(s) of a product in a particular country.

Further, faced with major budget constraints, many European countries have resorted to price cuts that affect both innovative and generic pharmaceuticals although in some countries it has disproportionately affected generic products. See ITEM 1A. RISK FACTORS Risks Related to Our Business Global economic conditions could harm us. in this Annual Report. In addition, some EU countries such as France, Serbia and Spain, recently had to address statements and rumors claiming that generics are not as safe and effective as reference drugs, which undermines efforts to increase generic utilization rates.

Substitution of biological drugs is not feasible in many European countries and the innovative industry continues its efforts to prevent automatic substitution of biosimilars and to assign different names to original and follow-on biologics.

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***Canada***

In Canada, pharmaceutical manufacturers are regulated by the Therapeutic Products Directorate ( TPD ) which derives its authority from the Canadian federal government under the Food and Drugs Act and the Controlled Drug and Substances Act. The TPD evaluates and monitors the safety, effectiveness and quality of pharmaceutical products. Products are officially approved for marketing in Canada following receipt of a market authorization, or Notice of Compliance (NOC), which is subject to the Food and Drug Regulations. Issuance of a Notice of Compliance for generic drug products is also subject to the Patented Medicines (Notice of Compliance) Regulations under the Patent Act.

Each Canadian province provides a comprehensive public drug program, which controls drug pricing and reimbursement and is responsible for ensuring eligible patients receive drugs through public funding. Pharmaceutical products available to patients are listed on provincial Drug Benefit Formularies. Currently, Canada's provinces are looking at national competitive bidding processes/tendering of drugs, which may affect the sustainability of the industry and the supply of pharmaceuticals.

Finally, Canada is involved in two major trade negotiations, one with the European Union (CETA), and the second one with ten Pacific countries including the United States (Trans Pacific Partnership), both of which could delay generic competition, for example, by changing Canada's IP framework to require the adoption of patent term extensions.

***Australia***

Pharmaceutical manufacturers and products are regulated in Australia by the Therapeutic Goods Administration ( TGA ) which oversees the quality, safety and efficacy of pharmaceutical products and other therapeutic goods. The TGA is a Division of the Australian Department of Health and Aging and established under the Therapeutic Goods Act of 1989.

Australian pharmaceutical manufacturers must be licensed under Part 3-3 of the Act, and their manufacturing facilities and processes must comply with good manufacturing practices in Australia. All pharmaceutical products manufactured for supply in Australia must be listed in the Australian Register of Therapeutic Goods ( ARTG ), before they can be marketed or supplied for sale in Australia.

The government regulates the pharmaceuticals market through the Pharmaceutical Benefits Scheme (PBS), which is a governmental healthcare program established to subsidize the cost of pharmaceuticals to Australian citizens. The PBS is operated under the National Health Act 1953. This statute legislates who may sell pharmaceutical products, pharmaceutical product pricing and governmental subsidies. More than 80% of all prescription medicines sold in Australia are reimbursed by the PBS. For pharmaceutical products listed on the PBS, the price is determined through negotiations between the Pharmaceutical Benefits Pricing Authority and pharmaceutical suppliers.

The government is conducting a Pharmaceutical Patents Review to evaluate whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry. The report is expected to be published at the end of April 2013. Further, the Productivity Commission is also conducting a review on the Compulsory Licensing that may affect the licensing of pharmaceutical products in Australia. This would pose a greater risk to brand products still under patent protection.

Australia is engaged in various trade negotiations, including the Trans Pacific Partnership that could have pricing implications for its patent and regulatory frameworks and affect the Pharmaceutical Benefits Scheme.

***Russia***

Federal legislation sets out the fundamentals of regulation in the sphere of health care. Federal Law on Pharmaceuticals No. 86-FZ of June 22, 1998 (as amended on December 18, 2006) (the Pharmaceutical Law ) establishes the general framework of legal requirements applicable to circulation of pharmaceuticals, including development, production, trials, quality control, efficacy, safety, importation and sale.

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Given the importance to the public of the health care sector, and providing the population with safe and high quality pharmaceuticals, the Pharmaceutical Law makes it a priority for the state to control the production, quality, efficacy, and safety of pharmaceuticals.

Russia's pharmaceutical market consists largely of an out-of-pocket retail market (70% of total market value), and the retail market is driven by promotion of branded products (whether originator or branded generics). A trend of increases in the cost of health care has drawn public scrutiny. Budget constraints and lower government revenue may impact timing of market entry and/or adversely affect pricing, and compel the government to resort to a tendering model. This could create new challenges particularly for foreign companies, as along with downward pricing pressures, Russia tends to favor domestically based producers.

Some foreign manufacturers, particularly in the pharmaceutical sector, have registered their wholly-owned subsidiaries in Russia. They then sell directly to their own companies registered in Russia who import for their own account. This approach affords full control of the supplier over distribution and helps to further reduce possible risks from relying on independent importers and distributors. For example, Actavis owns and operates a solid dosage manufacturing site in Podolsk, and employs more than 400 people, including regional representatives in 34 major regional centers. On the Russian market Actavis supplies both OTC medicines and prescription drugs, focusing on the delivery of drugs for the treatment of the most relevant diseases and conditions, such as medicines for treating the nervous and cardiovascular systems.

### **Environmental Matters**

We are subject to federal, state, and local environmental laws and regulations in the United States and abroad. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each jurisdiction where we have a business presence. Although we continue to make capital expenditures for environmental protection, we do not anticipate any significant expenditure in order to comply with such laws and regulations that would have a material impact on our earnings or competitive position. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse effect on our financial position. We cannot assure you, however, that environmental problems relating to facilities owned or operated by us will not develop in the future, and we cannot predict whether any such problems, if they were to develop, could require significant expenditures on our part. In addition, we are unable to predict what legislation or regulations may be adopted or enacted in the future with respect to environmental protection and waste disposal. See ITEM 1A. RISK FACTORS - Risks Related to Our Business - Our business will continue to expose us to risks of environmental liabilities in this Annual Report.

### **Seasonality**

There are no significant seasonal aspects that are expected to materially impact our business.

### **Backlog**

As a result of the extent of our supply chain, backlog of orders is not material to our business.

### **Employees**

As of December 31, 2012, we had approximately 17,700 employees. Of our employees, approximately 2,000 were engaged in R&D, 6,900 in manufacturing, 1,500 in quality assurance and quality control, 6,150 in sales, marketing and distribution, and 1,150 in administration.

## **ITEM 1A. RISK FACTORS**

### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Any statements made in this report that are not statements of historical fact or that refer to estimated or anticipated future events are forward-looking statements. We have based our forward-looking statements on management's beliefs and assumptions based on information available to our management at the time these statements are made. Such forward-looking statements reflect our current perspective of our business, future

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performance, existing trends and information as of the date of this filing. These include, but are not limited to, our beliefs about future revenue and expense levels and growth rates, prospects related to our strategic initiatives and business strategies, including the integration of, and synergies associated with, strategic acquisitions, express or implied assumptions about government regulatory action or inaction, anticipated product approvals and launches, business initiatives and product development activities, assessments related to clinical trial results, product performance and competitive environment, and anticipated financial performance. Without limiting the generality of the foregoing, words such as *may*, *will*, *expect*, *believe*, *anticipate*, *plan*, *intend*, *could*, *would*, *should*, *estimate*, *continue*, *or pursue*, or the negative thereof or comparable terminology, are intended to identify forward-looking statements. The statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We caution the reader that these statements are based on certain assumptions, risks and uncertainties, many of which are beyond our control. In addition, certain important factors may affect our actual operating results and could cause such results to differ materially from those expressed or implied by forward-looking statements. We believe the risks and uncertainties discussed under the section entitled **Risks Related to Our Business**, and other risks and uncertainties detailed herein and from time to time in our SEC filings, may cause our actual results to vary materially from those anticipated in any forward-looking statement.

We disclaim any obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

### **Risks Related to Our Business**

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this Annual Report. These and other risks could have a material adverse effect on our business, results of operations, financial condition and cash flows.

### **Risks Associated With Investing In the Business of Actavis**

#### ***Our operating results and financial condition may fluctuate.***

Our operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. The following events or occurrences, among others, could cause fluctuations in our financial performance from period to period:

development of new competitive products or generics by others;

the timing and receipt of approvals by the FDA and other regulatory authorities, including foreign regulatory authorities;

the failure to obtain, delay in obtaining or restrictions or limitations on approvals from the FDA or foreign regulatory authorities;

difficulties or delays in resolving FDA-observed deficiencies at our manufacturing facilities, which could delay our ability to obtain approvals of pending FDA product applications or curtail availability to continue production of existing products;

delays or failures in clinical trials that affect our ability to achieve FDA approvals or approvals from other foreign regulatory authorities;

serious or unexpected health or safety concerns with our products or product candidates;

changes in the amount we spend to develop, acquire or license new products, technologies or businesses;



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changes in the amount we spend to promote our products;

delays between our expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;

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changes in treatment practices of physicians that currently prescribe our products;

changes in coverage and reimbursement policies of health plans and other health insurers, including changes that affect newly developed or newly acquired products;

changes in laws and regulations concerning coverage and reimbursement of pharmaceutical products, including changes to Medicare, Medicaid, and similar programs;

increases in the cost of raw materials used to manufacture our products;

realization of assets and settlement of liabilities at amounts equal to estimated fair value as of the acquisition date;

manufacturing and supply interruptions, including failure to comply with manufacturing specifications;

the effect of economic changes in hurricane, monsoon, earthquake and other natural disaster-affected areas;

the impact of third party patents and other intellectual property rights which we may be found to infringe, or may be required to license, and the potential damages or other costs we may be required to pay as a result of a finding that we infringe such intellectual property rights or a decision that we are required to obtain a license to such intellectual property rights;

changes in antitrust laws and regulations concerning settlement of patent and other intellectual property disputes, and potential damages or other costs we may be required to pay as a result of such changes;

the mix of products that we sell during any time period;

lower than expected demand for our products;

our responses to price competition;

our ability to successfully integrate and commercialize the products, technologies and businesses we acquire or license, as applicable;

expenditures as a result of legal actions;

market acceptance of our products;

the impairment and write-down of goodwill or other intangible assets;

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disposition of our primary products, technologies and other rights;

termination or expiration of, or the outcome of disputes relating to, trademarks, patents, license agreements and other rights;

changes in insurance rates for existing products and the cost and availability of insurance for new and existing products;

general economic and industry conditions, including changes in interest rates affecting returns on cash balances and investments that affect customer demand;

our level of R&D activities;

impairment or write-down of investments or long-lived assets;

costs and outcomes of any tax audits;

fluctuations in foreign currency exchange rates;

costs and outcomes of any litigation involving intellectual property, drug pricing or reimbursement, product liability, customers or other issues;

timing of revenue recognition related to licensing agreements and/or strategic collaborations; and

risks related to the growth of our business across numerous countries world-wide and the inherent international economic, regulatory, political and business risks.

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As a result, we believe that period-to-period comparisons of our results of operations are not necessarily meaningful, and these comparisons should not be relied upon as an indication of future performance. The above factors may cause our operating results to fluctuate and adversely affect our financial condition and results of operations.

***Our substantial debt and other financial obligations could impair our financial condition and our ability to fulfill our debt obligations. Any refinancing of this substantial debt could be at significantly higher interest rates.***

As of December 31, 2012, we had total debt of approximately \$6.4 billion. Our substantial indebtedness and other financial obligations could:

impair our ability to obtain financing in the future for working capital, capital expenditures, acquisitions or general corporate purposes;

have a material adverse effect on us if we fail to comply with financial and affirmative and restrictive covenants in our debt agreements and an event of default occurs as a result of a failure that is not cured or waived;

require us to dedicate a substantial portion of our cash flow for interest payments on our indebtedness and other financial obligations, thereby reducing the availability of our cash flow to fund working capital and capital expenditures;

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and

place us at a competitive disadvantage compared to our competitors that have proportionally less debt.

Additionally, certain of our financing agreements may contain cross-default or other similar provisions whereby a default under one financing agreement could result in a default under our other financing agreements.

If we are unable to meet our debt service obligations and other financial obligations, we could be forced to restructure or refinance our indebtedness and other financial transactions, seek additional equity capital or sell our assets. We might then be unable to obtain such financing or capital or sell our assets on satisfactory terms, if at all. Any refinancing of our indebtedness could be at significantly higher interest rates, and/or incur significant transaction fees.

***If we do not successfully integrate Actavis into our business operations, our business could be adversely affected.***

We will need to successfully integrate the operations of the former Actavis Group with our business operations. Integrating the operations of the former Actavis Group with that of our own will be a complex and time-consuming process. Prior to the Actavis Group acquisition, it operated independently, with its own business, corporate culture, locations, employees and systems. There may be substantial difficulties, costs and delays involved in any integration of the business of the former Actavis Group with that of our own. These may include:

distracting management from day-to-day operations;

potential incompatibility of corporate cultures;

an inability to achieve synergies as planned;

costs and delays in implementing common systems and procedures; and

increased difficulties in managing our business due to the addition of international locations. Many of these risks may be accentuated because the majority of the former Actavis group's operations, employees and customers are located outside of the United States. Any one or all of these factors may increase operating costs or lower anticipated financial performance. Many of these factors are also outside of our control.

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Achieving anticipated synergies and the potential benefits underlying our reasons for the Actavis Group acquisition will depend on successful integration of the businesses. The failure to integrate the business operations of the former Actavis Group successfully would have a material adverse effect on our business, financial condition and results of operations.

*If we are unable to successfully develop or commercialize new products, our operating results will suffer.*

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize new brand and generic products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;

receiving requisite regulatory approvals for such products in a timely manner or at all;

the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;

developing and commercializing a new product is time consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development and commercialization of new products;

experiencing delays as a result of limited resources at FDA or other regulatory agencies;

changing review and approval policies and standards at FDA and other regulatory agencies; and

commercializing generic products may be substantially delayed by the listing with the FDA of patents that have the effect of potentially delaying approval of a generic product by up to 30 months.

As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals, or approvals at all, necessary for marketing by us or other third-party partners. This risk particularly exists with respect to the development of proprietary products because of the uncertainties, higher costs and lengthy time frames associated with research and development of such products and the inherent unproven market acceptance of such products. Additionally, we face heightened risks in connection with our development of extended release or controlled release generic products because of the technical difficulties and regulatory requirements related to such products. Additionally, with respect to generic products for which we are the first applicant to request approval on the basis that an innovator patent is invalid or not infringed (a paragraph IV filing), our ability to obtain 180 days of generic market exclusivity may be contingent on our ability to obtain FDA approval or tentative approval within 30 months of FDA's acceptance of our application for filing. We therefore risk forfeiting such market exclusivity if we are unable to obtain such approval or tentative approval on a timely basis. If any of our products are not timely approved or, when acquired or developed and approved, cannot be successfully manufactured or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

*Our brand pharmaceutical expenditures may not result in commercially successful products.*

Developing and commercializing brand pharmaceutical products is generally more costly than generic products. In the future, we anticipate continuing our product development expenditures for our Actavis Specialty Brands business segment. For example in 2012, we initiated a Phase 3 clinical trial for our Esmya™ product for treatment of uterine fibroids. Such clinical trials are costly and may not result in successful outcomes. We cannot be sure that our business expenditures, including but not limited to our expenditures related to our Esmya™ product, will result in the successful discovery, development or launch of brand products that will prove to be commercially successful or will improve the long-term profitability of our business. If such business expenditures do not result in successful discovery, development or launch of commercially successful brand products our results of operations and financial condition could be materially adversely affected.



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***Our investments in biosimilar products may not result in products that are approved by the FDA or other ex-U.S. regulatory authorities and, even if approved by such authorities, may not result in commercially successful products.***

In 2011, we entered into an agreement with Amgen to collaborate on the development and commercialization of biosimilar products. Under the agreement, we will be required to invest up to \$400.0 million in furtherance of the development and regulatory approval of such products. Although Amgen, our development partner, has substantial expertise and experience in the development of biological products, significant uncertainty remains concerning the regulatory pathway in the United States and in other countries to obtain regulatory approval of biosimilar products, and the commercial pathway to successfully market and sell such products. In particular, although recently enacted legislation authorizes the FDA to establish a regulatory pathway for the review and approval of such products, to date no such pathway has been established. Even if FDA enacts rules and regulations concerning the development and approval of follow on biosimilars, such regulations could include provisions that provide up to twelve or more years of exclusive marketing rights for the original developer of the product on which a follow on biosimilar product is based. Additionally, biosimilar products will likely be subject to extensive patent clearances and/or patent infringement litigation, which could delay or prevent the commercial launch of a product for many years. Further, our collaboration with Amgen may not result in products that meet the requirements established by the FDA or other ex-U.S. regulatory authorities. If our collaboration does result in biosimilar products that obtain FDA or other ex-U.S. regulatory authority approval, such product(s) may not be commercially successful and/or may not generate profits in amounts that are sufficient to offset the amount invested to obtain such approvals. Market success of biosimilar products will depend on demonstrating to patients, physicians and payors that such products are safe and efficacious compared to other existing products yet offer a more competitive price or other benefit over existing therapies. If our collaboration with Amgen does not result in the development and timely approval of biosimilar products or if such products, once developed and approved, are not commercially successful, our results of operations, financial condition and cash flows could be materially adversely affected.

***Any acquisitions of technologies, products and businesses, may be difficult to integrate, could adversely affect our relationships with key customers, and/or could result in significant charges to earnings.***

We regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate products, technologies, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

In addition, as a result of acquiring businesses or products, or entering into other significant transactions, we have experienced, and will likely continue to experience, significant charges to earnings for merger and related expenses. These costs may include substantial fees for investment bankers, attorneys, accountants, and severance and other closure costs associated with the elimination of duplicate or discontinued products, operations and facilities. Charges that we may incur in connection with acquisitions could adversely affect our results of operations for particular quarterly or annual periods.



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### ***If we are unsuccessful in our joint ventures and other collaborations, our operating results could suffer.***

We have made substantial investments in joint ventures and other collaborations and may use these and other methods to develop or commercialize products in the future. These arrangements typically involve other pharmaceutical companies as partners that may be competitors of ours in certain markets. In many instances, we will not control these joint ventures or collaborations or the commercial exploitation of the licensed products, and cannot assure you that these ventures will be profitable. Although restrictions contained in certain of these programs have not had a material adverse impact on the marketing of our own products to date, any such marketing restrictions could affect future revenues and have a material adverse effect on our operations. Our results of operations may suffer if existing joint venture or collaboration partners withdraw, or if these products are not timely developed, approved or successfully commercialized.

### ***If we are unable to adequately protect our technology or enforce our patents, our business could suffer.***

Our success with the brand products that we develop will depend, in part, on our ability to obtain patent protection for these products. We currently have a number of U.S. and foreign patents issued and pending. However, issuance of a patent is not conclusive evidence of its validity or enforceability. We cannot be sure that we will receive patents for any of our pending patent applications or any patent applications we may file in the future, or that our issued patents will be upheld if challenged. If our current and future patent applications are not approved or, if approved, our patents are not upheld in a court of law if challenged, it may reduce our ability to competitively exploit our patented products. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially market these products may be diminished. For example, in October 2011, we received notice that competitors had filed ANDAs seeking approval to market a generic version of our Generess<sup>®</sup> Fe product prior to expiration of the patents that protect the product. Our licensor, Warner-Chilcott Company filed suit against both ANDA filers in November and December of 2011. Additionally, patents covering our Androderm<sup>®</sup> and INFed<sup>®</sup> products have expired and we have no further patent protection on these products. Therefore, it is possible that a competitor may launch a generic version of Androderm<sup>®</sup> and/or INFed<sup>®</sup> at any time, which would result in a significant decline in that product's revenue and profit. Both of these products were significant contributors to our Actavis Specialty Brands business in 2012.

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 that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets will become known or independently developed by our competitors.

If we are unable to adequately protect our technology, trade secrets or propriety know-how, or enforce our intellectual property rights, our results of operations, financial condition and cash flows could suffer.

### ***If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, our sales of generic products may suffer.***

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

making changes to the formulation of the brand product and arguing that potential generic competitors must demonstrate bioequivalency or comparable abuse-resistance to the reformulated brand product;

pursuing new patents for existing products which may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;

selling the brand product as an Authorized Generic, either by the brand company directly, through an affiliate or by a marketing partner;

using the Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;



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seeking changes to U.S. Pharmacopeia, an organization which publishes industry recognized compendia of drug standards;

attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled;

using the legislative and regulatory process to set definitions of abuse deterrent formulations to protect brand company patents and profits;

attaching patent extension amendments to non-related federal legislation;

engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing;

entering into agreements with pharmacy benefit management companies which have the effect of blocking the dispensing of generic products; and

seeking patents on methods of manufacturing certain API.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

***If competitors are successful in limiting competition for certain generic products through their legislative, regulatory and litigation efforts, our sales of certain generic products may suffer.***

Certain of our competitors have recently challenged our ability to distribute Authorized Generics during the competitors' 180-day period of ANDA exclusivity under the Hatch-Waxman Act. Under the challenged arrangements, we have obtained rights to market and distribute under a brand manufacturer's NDA a generic alternative of the brand product. Some of our competitors have challenged the propriety of these arrangements by filing Citizen Petitions with the FDA, initiating lawsuits alleging violation of the antitrust and consumer protection laws, and seeking legislative intervention. For example, legislation has been introduced in the U.S. Senate that would prohibit the marketing of Authorized Generics during the 180-day period of ANDA exclusivity under the Hatch-Waxman Act. If distribution of Authorized Generic versions of brand products is otherwise restricted or found unlawful, our results of operations, financial condition and cash flows could be materially adversely affected.

***From time to time we may need to rely on licenses to proprietary technologies, which may be difficult or expensive to obtain.***

We may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market our products may be inhibited or prevented, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.***

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. This is especially true in the case of generic products on which the patent covering the brand product is expiring, an area where infringement litigation is prevalent, and in the case of new brand products where a competitor has obtained patents for similar products. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. In addition, if we infringe the rights of others, we could lose our right to develop, manufacture or market products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. For example, we are engaged in litigation with Momenta Pharmaceuticals concerning whether our distribution and sale of enoxaparin infringes Momenta's U.S. Patent

No. 7,575,886, and we continue to market enoxaparin.

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Similarly, we are engaged in litigation with Duramed Pharmaceuticals concerning whether our Amethia<sup>™</sup> product infringes Duramed's U.S. Patent 7,320,969 and we continue to manufacture and market our Amethia<sup>™</sup> product. Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on commercially reasonable terms, or at all. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could result in substantial monetary damage awards and could prevent us from manufacturing and selling a number of our products, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. See *Legal Matters* in NOTE 18 *Commitments and Contingencies* in the accompanying *Notes to Consolidated Financial Statements* in this Annual Report.

***Our distribution operations are highly dependent upon a primary courier service.***

Product deliveries within our Anda Distribution business are highly dependent on overnight delivery services to deliver our products in a timely and reliable manner, typically by overnight service. Our Anda Distribution business ships a substantial portion of products via one courier's air and ground delivery service. If the courier terminates our contract or if we cannot renew the contract on favorable terms or enter into a contract with an equally reliable overnight courier to perform and offer the same service level at similar or more favorable rates, our business, results of operations, financial condition and cash flows could be materially adversely affected.

***Our distribution operations concentrate on generic products and therefore are subject to the risks of the generic industry.***

The ability of our Anda Distribution business to provide consistent, sequential quarterly growth is affected, in large part, by our participation in the launch of new products by generic manufacturers and the subsequent advent and extent of competition encountered by these products. This competition can result in significant and rapid declines in pricing with a corresponding decrease in net sales of our Anda Distribution business. Our margins can also be affected by the risks inherent to the generic industry, which is discussed below under *Risks Relating to Investing in the Pharmaceutical Industry*.

***Our distribution operations compete directly with significant customers of our generic and brand businesses.***

In our Anda Distribution business, our main competitors are McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc. These companies are significant customers of our Actavis Pharma and Actavis Specialty Brands operations and collectively accounted for approximately 30% of our annual net revenues in 2012. Our activities related to our Anda Distribution business, as well as the acquisition of other businesses that compete with our customers, may result in the disruption of our business, which could harm relationships with our current customers, employees or suppliers, and could adversely affect our expenses, pricing, third-party relationships and revenues. Further, a loss of a significant customer of our Actavis Pharma or Actavis Specialty Brands operations could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***If we are unable to obtain sufficient supplies from key manufacturing sites or 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.***

We are required to identify the supplier(s) of all the raw materials for our products in our applications with the FDA and other regulatory agencies. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some products and raw materials are available only from a single source and, in many of our drug applications, only one supplier of products and raw materials or site of manufacture has been identified, even in instances where multiple sources exist. Some of these products have historically accounted for a significant portion of our revenues, such as INFed<sup>®</sup>, metoprolol succinate extended release tablets,

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methylphenidate hydrochloride extended release tablets, and a significant number of our oral contraceptive and controlled substance products. From time to time, certain of our manufacturing sites or outside suppliers have experienced regulatory or supply-related difficulties that have inhibited their ability to deliver products and raw materials to us, causing supply delays or interruptions. To the extent any difficulties experienced by our manufacturing sites or suppliers cannot be resolved or extensions of our key supply agreements cannot be negotiated within a reasonable time and on commercially reasonable terms, or if raw materials for a particular product become unavailable from an approved supplier and we are required to qualify a new supplier with the FDA, or if we are unable to do so, our profit margins and market share for the affected product could decrease or be eliminated, as well as delay our development and sales and marketing efforts. Such outcomes could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Our manufacturing sites outside of the United States and our arrangements with foreign suppliers are subject to certain additional risks, including the availability of government clearances, export duties, political instability, war, acts of terrorism, currency fluctuations and restrictions on the transfer of funds. For example, 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 and foreign regulatory body regulation, customs clearances, various import duties and other government clearances, as well as potential shipping delays due to inclement weather, political instability, strikes or other matters outside of our control. 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, recent 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.

***Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers, may reduce our revenues in future fiscal periods.***

Consistent with industry practice we, like many generic product manufacturers, have liberal return policies and have been willing to give customers post-sale inventory allowances. Under these arrangements, from time to time, we may give our customers credits on our generic products that our customers hold in inventory after we have decreased the market prices of the same generic products. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, we may reduce the price of our product. As a result, we may be obligated to provide significant credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to us by our wholesale customer for a particular product and the negotiated price that the wholesaler's customer pays for that product. Although we establish reserves based on our prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates, which could have a material adverse effect on our results of operations, financial condition, cash flows and the market price of our stock.

***Investigations of the calculation of average wholesale prices may adversely affect our business.***

Many government and third-party payers, including Medicare, Medicaid, HMOs and MCOs, have historically reimbursed doctors, pharmacies and others for the purchase of certain prescription drugs based on a drug's AWP or wholesale acquisition cost (WAC). In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP and WAC, in which they have suggested that reporting of inflated AWP's or WAC's have led to excessive payments for prescription drugs. For example, beginning in July 2002, we and certain of our subsidiaries, as well as numerous other pharmaceutical companies, were named as defendants in various state and federal court actions alleging improper or fraudulent practices related to the reporting of AWP and/or WAC of certain products, and other improper acts, in order to increase prices and market shares. Additional actions are anticipated. These actions, if successful, could adversely affect us and may have a material adverse effect on our business, results of

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operations, financial condition and cash flows. See *Legal Matters* in NOTE 18 *Commitments and Contingencies* in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

***The design, development, manufacture and sale of our products involves the risk of product liability claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.***

The design, development, manufacture and sale of our products involve an inherent risk of product liability claims and the associated adverse publicity. Insurance coverage is expensive and may be difficult to obtain, and may not be available in the future on acceptable terms, or at all. We regularly monitor the use of our products for trends or increases in reports of adverse events or product complaints, and regularly report such matters to the FDA. In some, but not all, cases an increase in adverse event reports may be an indication that there has been a change in a product's specifications or efficacy. Such changes could lead to a recall of the product in question or, in some cases, increases in product liability claims related to the product in question. If the coverage limits for product liability insurance policies are not adequate or if certain of our products are excluded from coverage, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows. See *Legal Matters* in NOTE 18 *Commitments and Contingencies* in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

***The loss of our key personnel could cause our business to suffer.***

The success of our present and future operations will depend, to a significant extent, upon the experience, abilities and continued services of key personnel. For example, although we have other senior management personnel, a significant loss of the services of Paul Bisaro, our Chief Executive Officer, or other senior executive officers without having or hiring a suitable successor, could cause our business to suffer. We cannot assure you that we will be able to attract and retain key personnel. We have entered into employment agreements with many of our senior executive officers but such agreements do not guarantee that our senior executive officers will remain employed by us for a significant period of time, or at all. We do not carry key-employee life insurance on any of our officers.

***Significant balances of intangible assets, including product rights and goodwill acquired, are subject to impairment testing and may result in impairment charges, which will adversely affect our results of operations and financial condition.***

A significant amount of our total assets is related to acquired intangibles and goodwill. As of December 31, 2012, the carrying value of our product rights and other intangible assets was approximately \$3.83 billion and the carrying value of our goodwill was approximately \$4.76 billion.

Our product rights are stated at cost, less accumulated amortization. We determine original fair value and amortization periods for product rights based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired products. Such factors include the product's position in its life cycle, the existence or absence of like products in the market, various other competitive and regulatory issues and contractual terms. Significant adverse changes to any of these factors would require us to perform an impairment test on the affected asset and, if evidence of impairment exists, we would be required to take an impairment charge with respect to the asset. Such a charge could have a material adverse effect on our results of operations and financial condition.

Our other significant intangible assets include acquired core technology and customer relationships, which are intangible assets with definite lives, our Andax trade name and acquired in-process research and development (IPR&D) intangibles, acquired in recent business acquisitions, which are intangible assets with indefinite lives.

Our acquired core technology and customer relationship intangible assets are stated at cost, less accumulated amortization. We determined the original fair value of our other intangible assets by performing a discounted cash flow analysis, which is based on our assessment of various factors. Such factors include existing operating margins, the number of existing and potential competitors, product pricing patterns, product market

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share analysis, product approval and launch dates, the effects of competition, customer attrition rates, consolidation within the industry and generic product lifecycle estimates. Our other intangible assets with definite lives are tested for impairment when there are significant changes to any of these factors. If evidence of impairment exists, we would be required to take an impairment charge with respect to the impaired asset. Such a charge could have a material adverse effect on our results of operations and financial condition.

Goodwill, our Anda trade name intangible asset and our IPR&D intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. A goodwill, trade name or IPR&D impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

***We may need to raise additional funds in the future which may not be available on acceptable terms or at all.***

We may consider issuing additional debt or equity securities in the future to fund potential acquisitions or investments, to refinance existing debt, or for general corporate purposes. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses and potentially lower our credit ratings. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements.

***Our business could suffer as a result of manufacturing difficulties or delays.***

The manufacture of certain of our products and product candidates, particularly our controlled-release products, transdermal products, injectable products, and our oral contraceptive products, is more difficult than the manufacture of immediate-release products. Successful manufacturing of these types of products requires precise manufacturing process controls, API that conforms to very tight tolerances for specific characteristics and equipment that operates consistently within narrow performance ranges. Manufacturing complexity, testing requirements, and safety and security processes combine to increase the overall difficulty of manufacturing these products and resolving manufacturing problems that we may encounter.

Our manufacturing and other processes utilize sophisticated equipment, which sometimes require a significant amount of time to obtain and install. Our business could suffer if certain manufacturing or other equipment, or a portion or all of our facilities were to become inoperable for a period of time. This could occur for various reasons, including catastrophic events such as earthquake, monsoon, hurricane or explosion, unexpected equipment failures or delays in obtaining components or replacements thereof, as well as construction delays or defects and other events, both within and outside of our control. Our inability to timely manufacture any of our significant products could have a material adverse effect on our results of operations, financial condition and cash flows.

***Our business will continue to expose us to risks of environmental liabilities.***

Our product and API development programs, manufacturing processes and distribution logistics involve the controlled use of hazardous materials, chemicals and toxic compounds in our owned and leased facilities. As a result, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous materials and the discharge of pollutants into the air and water. Our programs and processes expose us to risks that an accidental contamination could result in (i) our noncompliance with such environmental laws and regulations and (ii) regulatory enforcement actions or claims for personal injury and property damage against us. If an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable



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for cleanup obligations, damages and fines. The substantial unexpected costs we may incur could have a material and adverse effect on our business, results of operations, financial condition, and cash flows. In addition, environmental permits and controls are required for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Any modification, revocation or non-renewal of our environmental permits could have a material adverse effect on our ongoing operations, business and financial condition. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased development or manufacturing activities at any of our facilities.

### ***Global economic conditions could harm us.***

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies during 2010, 2011 and continuing in 2012. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global real estate markets have contributed to increased market volatility and diminished expectations for western and emerging economies. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have resulted in a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business consumer spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our customers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

### ***Our foreign operations may become less attractive if political and diplomatic relations between the United States and any country where we conduct business operations deteriorates.***

The relationship between the United States and the foreign countries where we conduct business operations may weaken over time. Changes in the state of the relations between any such country and the United States are difficult to predict and could adversely affect our future operations. This could lead to a decline in our profitability. Any meaningful deterioration of the political and diplomatic relations between the United States and the relevant country could have a material adverse effect on our operations.

### ***Our global operations expose us to risks and challenges associated with conducting business internationally.***

We operate on a global basis with offices or activities in Europe, Iceland, Africa, Asia, South America, Australasia and North America. We face several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to our international operations. These laws and regulations include data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import and trade restrictions, export requirements, U.S. laws such as the Foreign Corrupt Practices Act, and other U.S. federal laws and regulations established by the office of Foreign Asset Control, local laws such as the UK Bribery Act 2010 or other local laws which prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, however, there is a risk that some provisions may be inadvertently breached by us, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements, or otherwise. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability

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to attract and retain employees, our business and our operating results. Our success depends, in part, on our ability to anticipate these risks and manage these challenges. These factors or any combination of these factors may adversely affect our revenue or our overall financial performance. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our operating results. Our success depends, in part, on our ability to anticipate these risks and manage these difficulties.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

political and economic instability;

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;

difficulties and costs of staffing and managing foreign operations;

difficulties protecting or procuring intellectual property rights; and

fluctuations in foreign currency exchange rates.

These factors or any combination of these factors may adversely affect our revenue or our overall financial performance.

### ***We have exposure to tax liabilities.***

As a multinational corporation, we are subject to income taxes as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. Recent proposals by the current U.S. administration for fundamental U.S. international tax reform, including without limitation provisions that would limit the ability of U.S. multinationals to defer U.S. taxes on foreign income, if enacted, could have a significant adverse impact on our effective tax rate following the Actavis Group acquisition.

### ***Foreign currency fluctuations could adversely affect our business and financial results.***

We do business and generate sales in numerous countries outside the United States. As such, foreign currency fluctuations may affect the costs that we incur in such international operations. Some of our operating expenses are incurred in non-U.S. dollar currencies. The appreciation of non-U.S. dollar currencies in those countries where we have operations against the U.S. dollar could increase our costs and could harm our results of operations and financial condition.

### ***Prior to the Actavis Group acquisition, the Actavis Group was a privately-held company and its new obligations of being a part of a public company may require significant resources and management attention.***

As a result of the Actavis Group acquisition, the Actavis companies became subsidiaries of our consolidated company, and will need to comply with the Sarbanes-Oxley Act of 2002 and the rules and regulations subsequently implemented by the SEC and the Public Company Accounting Oversight Board. We will need to ensure that we establish and maintain effective disclosure controls as well as internal controls and procedures for financial reporting, and such compliance efforts may be costly and may divert the attention of management.



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***We have incurred and will continue to incur significant transaction, integration and restructuring costs in connection with the Actavis Group acquisition.***

We have incurred and will continue to incur significant transaction costs related to the Actavis Group acquisition. In addition, we will incur integration and restructuring costs as we integrate the legacy Actavis businesses. Although we expect that the realization of benefits and efficiencies related to the integration of the businesses may offset these transaction costs, integration and restructuring costs over time, no assurances can be made that this net benefit will be achieved in the near term, or at all, which could adversely affect our financial condition and results of operations.

***A write-off of a significant portion of the goodwill and other intangibles recorded in connection with the Actavis Group acquisition would negatively affect the combined company's financial results.***

Upon consummation of the Actavis Group acquisition, we recorded goodwill of approximately \$2,813.9 million. On at least an annual basis, we assess whether there has been an impairment in the value of goodwill. If the carrying value of goodwill exceeds its estimated fair value, impairment is deemed to have occurred, and the carrying value of goodwill is written down to fair value. Under current accounting rules, this would result in a charge to the combined company's operating earnings. Accordingly, any determination requiring the write-off of a significant portion of goodwill recorded in connection with the Actavis Group acquisition would negatively affect our results of operations. We also allocated approximately \$2,378.1 million of the total consideration paid in connection with the Actavis Group acquisition to identified intangibles representing currently marketed products ( CMP ) and approximately \$194.4 million to identified in-process research and development ( IPR&D ) intangible products. The CMP and IPR&D amounts will be subject to future impairment testing if market conditions for the underlying products experience a significant adverse change. If evidence of impairment exists, we would be required to take an impairment charge to our operating earnings, which could have a material adverse effect on our results of operations.

***Substantial amounts of our information concerning our products, customers, employees and ongoing business are stored digitally and is subject to threats of theft, tampering, or other intrusion.***

We collect and maintain information in digital form that is necessary to conduct our business. This digital information includes, but is not limited to, confidential and proprietary information as well as personal information regarding our customers and employees. Data maintained in digital form is subject to the risk of intrusion, tampering, and theft. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for the processing, transmission and storage of digital information. However, the development and maintenance of these systems is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly more sophisticated. Despite our efforts, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. In addition, we provide confidential, proprietary and personal information to third parties when it is necessary to pursue our business objectives. While we obtain assurances that these third parties will protect this information and, where appropriate, monitor the protections employed by these third parties, there is a risk the confidentiality of data held by third parties may be compromised. If our data systems are compromised, our business operations may be impaired, we may lose profitable opportunities or the value of those opportunities may be diminished, and we may lose revenue as a result of unlicensed use of our intellectual property. If personal information of our customers or employees is misappropriated, our reputation with our customers and employees may be injured resulting in loss of business and/or morale, and we may incur costs to remediate possible injury to our customers and employees or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents.

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### **Risks Relating To Investing In the Pharmaceutical Industry**

*Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.*

All pharmaceutical companies, including Actavis, Inc., are subject to extensive, complex, costly and evolving government regulation. For the U.S., this is principally administered by the FDA and to a lesser extent by the DEA and state government agencies, as well as by varying regulatory agencies in foreign countries where 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, and similar foreign statutes and regulations, govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products.

Under these regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA and similar ex-U.S. authorities, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or Warning Letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a Warning Letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We are also required to report adverse events associated with our products to FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in product liability claims, labeling changes, recalls, market withdrawals or other regulatory actions.

Our manufacturing facility in Corona, California is currently subject to a consent decree of permanent injunction. We cannot assure that the FDA will determine we have adequately corrected deficiencies at our Corona manufacturing site, that subsequent FDA inspections at any of our manufacturing sites will not result in additional inspectional observations at such sites, that approval of any of the pending or subsequently submitted NDAs, ANDAs or supplements to such applications by Actavis or our subsidiaries will be granted or that the FDA will not seek to impose additional sanctions against Actavis or any of its subsidiaries. The range of possible sanctions includes, among others, FDA issuance of adverse publicity, product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition and cash flows. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. Although we have instituted internal compliance programs, if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business. Certain of our vendors are subject to similar regulation and periodic inspections.

The process for obtaining governmental approval to manufacture and market pharmaceutical products is rigorous, time-consuming and costly, and we cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental or third-party approvals prior to manufacturing, marketing and shipping our products. Consequently, there is always the chance that we will not obtain FDA or other necessary approvals, or that the rate, timing and cost of obtaining such approvals, will adversely affect our product introduction plans or results of operations. We carry inventories of certain product(s) in anticipation of launch, and if such product(s) are not subsequently launched, we may be required to write-off the related inventory.

Our And a Distribution operations and our customers are subject to various regulatory requirements, including requirements from the DEA, FDA, state boards of pharmacy and city and county health regulators, among others. These include licensing, registration, recordkeeping, security and reporting requirements. The DEA requires our And a Distribution business to monitor customer orders of DEA Scheduled Drugs and to report suspicious orders to the DEA. Any determination by the DEA that we have failed to comply with applicable laws

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and regulations could result in DEA suspending, terminating or refusing to renew Anda Distribution's license to distribute Scheduled Drugs. Additionally, although physicians may prescribe FDA approved products for an off label indication, we are permitted to market our products only for the indications for which they have been approved. Some of our products are prescribed off label and FDA or other regulatory authorities could take enforcement actions if they conclude that we or our distributors have engaged in off label marketing. In addition, several states and the federal government have begun to enforce anti-counterfeit drug pedigree laws which require the tracking of all transactions involving prescription drugs beginning with the manufacturer, through the supply chain, and down to the pharmacy or other health care provider dispensing or administering prescription drug products. For example, effective July 1, 2006, the Florida Department of Health began enforcement of the drug pedigree requirements for distribution of prescription drugs in the State of Florida. Pursuant to Florida law and regulations, wholesalers and distributors, including our subsidiary, Anda Pharmaceuticals, are required to maintain records documenting the chain of custody of prescription drug products they distribute beginning with the purchase of products from the manufacturer. These entities are required to provide documentation of the prior transaction(s) to their customers in Florida, including pharmacies and other health care entities. Several other states have proposed or enacted legislation to implement similar or more stringent drug pedigree requirements. In addition, federal law requires that a non-authorized distributor of record must provide a drug pedigree documenting the prior purchase of a prescription drug from the manufacturer or from an authorized distributor of record. In cases where the wholesaler or distributor selling the drug product is not deemed an authorized distributor of record it would need to maintain such records. FDA had announced its intent to impose additional drug pedigree requirements (e.g., tracking of lot numbers and documentation of all transactions) through implementation of drug pedigree regulations which were to have taken effect on December 1, 2006. However, a federal appeals court has issued a preliminary injunction to several wholesale distributors granting an indefinite stay of these regulations pending a challenge to the regulations by these wholesale distributors.

***The supply of APIs into Europe may be negatively affected by recent regulations promulgated by the European Union.***

On July 2, 2013, all active pharmaceutical ingredients (APIs) imported into the European Union (EU) must be certified as complying with the good manufacturing practice (GMP) standards established by the EU, as stipulated by the International Conference for Harmonization (ICH Q7). These new regulations place the certification requirement on the regulatory bodies of the exporting countries. Accordingly, as of July 2, 2013, the national regulatory authorities of each exporting country must: (i) insure that all manufacturing plants within their borders that export API into the EU comply with EU manufacturing standards and; (ii) for each API exported, present a written document confirming that the exporting plant conforms to EU manufacturing standards. If not postponed or modified, the imposition of this responsibility on the governments of the nations exporting API may cause a shortage of API necessary to manufacture our products, as certain governments may not be willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API may cause us to have to cease manufacture of certain products, or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers unable to export. This could adversely affect the Company and could have a material adverse effect on our business, results of operations, financial condition and cash flow.

***Federal regulation of arrangements between manufacturers of brand and generic products could adversely affect our business.***

As part of the MMA, companies are required to file with the FTC and the Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of brand drugs. This requirement, as well as new legislation pending in U.S. Congress related to settlements between brand and generic drug manufacturers, could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The impact of this requirement, the pending legislation and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, is uncertain and could

adversely affect our business. For example, in January 2009, the FTC and the State of California filed a lawsuit

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against us alleging that our settlement with Solvay related to our ANDA for a generic version of Androgel® is unlawful. Numerous private parties purporting to represent various classes of plaintiffs filed similar lawsuits. We have also received requests for information and Statements of Objection in connection with investigations into settlements and other arrangements between competing pharmaceutical companies by the European Competition Commission. For example, two of our Arrow Group subsidiaries currently are the subject of a European Competition Commission Statement of Objection related to their 2002 and 2003 settlements of patent litigation related to citalopram. Any adverse outcome of these actions or investigations, or actions or investigations related to other settlements we have entered into, could have a material adverse effect on our business, results of operations, financial condition and cash flows. See *Legal Matters* in NOTE 18 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

***We are subject to federal and state healthcare fraud and abuse laws which may adversely affect our business.***

In the United States, most of our products are reimbursed under federal and state health care programs such as Medicaid, Medicare, TriCare, and or state pharmaceutical assistance programs. Many foreign countries have similar laws. Federal and state laws designed to prevent fraud and abuse under these programs prohibit pharmaceutical companies from offering valuable items or services to customers or potential customers to induce them to buy, prescribe, or recommend Actavis product (the so-called antikickback laws). Exceptions are provided for discounts and certain other arrangements if specified requirements are met. Other federal and state laws, and similar foreign laws, not only prohibit us from submitting any false information to government reimbursement programs but also prohibit us and our employees from doing anything to cause, assist, or encourage our customers to submit false claims for payment to these programs. Violations of the fraud and abuse laws may result in severe penalties against the responsible employees and Actavis, including jail sentences, large fines, and the exclusion of Actavis products from reimbursement under federal and state programs. Actavis is committed to conducting the sales and marketing of its products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions. For example, in December 2009, we learned that numerous pharmaceutical companies, including certain subsidiaries of the Company, have been named as defendants in a qui tam action pending in the United States District Court for the District of Massachusetts alleging that the defendants falsely reported to the United States that certain pharmaceutical products were eligible for Medicaid reimbursement and thereby allegedly caused false claims for payment to be made through the Medicaid program. Any adverse outcome of this action, or the imposition of penalties or sanctions for failing to comply with the fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. See *Legal Matters* in NOTE 18 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

***Healthcare reform and a reduction in the coverage and reimbursement levels by governmental authorities, HMOs, MCOs or other third-party payers may adversely affect our business.***

Demand for our products depends in part on the extent to which coverage and reimbursement is available from third-party payers, such as the Medicare and Medicaid programs and private payors. In order to commercialize our products, we have obtained from government authorities and private health insurers and other organizations, such as HMOs and MCOs, recognition for coverage and reimbursement at varying levels for the cost of certain of our products and related treatments. Third-party payers increasingly challenge pricing of pharmaceutical products. Further, the trend toward managed healthcare in the U.S., the growth of organizations such as HMOs and MCOs and legislative proposals to reform healthcare and government insurance programs create uncertainties regarding the future levels of coverage and reimbursement for pharmaceutical products. Such cost containment measures and healthcare reform could reduce reimbursement of our pharmaceutical products, resulting in lower prices and a reduction in the product demand. This could affect our ability to sell our products and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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There is uncertainty surrounding implementation of legislation involving payments for pharmaceuticals under government programs such as Medicare, Medicaid and Tricare. Depending on how existing provisions are implemented, the methodology for certain payment rates and other computations under the Medicaid Drug Rebate program reimbursements may be reduced or not be available for some of Actavis' products. Additionally, any reimbursement granted may not be maintained or limits on reimbursement available from third-party payers may reduce demand for, or negatively affect the price of those products. Ongoing uncertainty and challenges to the Affordable Care Act (ACA), including but not limited to, modification in calculation of rebates, mandated financial or other contributions to close the Medicare Part D coverage gap (donut hole), calculation of AMP, and other provisions could have a material adverse effect on our business. In addition, various legislative and regulatory initiatives in states, including proposed modifications to reimbursements and rebates, product pedigree and tracking, pharmaceutical waste (take-back) initiatives, and therapeutic category generic substitution carve-out legislation may also have a negative impact on the Company. Actavis maintains a full-time government affairs department in Washington, DC, which is responsible for coordinating state and federal legislative activities, and places a major emphasis in terms of management time and resources to ensure a fair and balanced legislative and regulatory arena.

***The pharmaceutical industry is highly competitive and our future revenue growth and profitability are dependent on our timely development and launches of new products ahead of our competitors.***

We face strong competition in our Actavis Pharma, Actavis Specialty Brands and Anda Distribution businesses. The intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of brand products to healthcare professionals in private practice, group practices and MCOs. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and drug-delivery systems. Based on total assets, annual revenues, and market capitalization, we are smaller than certain of our national and international competitors in the brand and distribution product arenas. Most of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. It is possible that developments by our competitors will make our products or technologies noncompetitive or obsolete.

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 for brand name products and related exclusivity periods expire, the first generic manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. Therefore, our ability to increase or maintain revenues and profitability in our generics business is largely dependent on our success in challenging patents and developing non-infringing formulations of proprietary products. As competing manufacturers receive regulatory approvals on similar products or as brand manufacturers launch generic versions of such products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, in some cases dramatically. Accordingly, the level of market share, revenue 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 margins. We may have fewer opportunities to launch significant generic products in the future, as the number and size of proprietary products that are subject to patent challenges is expected to decrease in the next several years compared to historical levels. Additionally, as new competitors enter the market, there may be increased pricing pressure on certain products, which would result in lower gross margins. This is particularly true in the case of certain Asian and other overseas generic competitors, who may be able to produce products at costs lower than the costs of domestic manufacturers. If we experience substantial competition from Asian or other overseas generic competitors with lower production costs, our profit margins will suffer.



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We also face strong competition in our Anda Distribution business, where we compete with a number of large wholesalers and other distributors of pharmaceuticals, including McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which market both brand and generic pharmaceutical products to their customers. These companies are significant customers of our Actavis Specialty Brands and Actavis Pharma businesses. As generic products generally have higher gross margins for distributors, 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 full line 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. The large wholesalers have historically not used telemarketers to sell to their customers, but recently have begun to do so. 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.

***Sales of our products may continue to be adversely affected by the continuing consolidation of our distribution network and the concentration of our customer base.***

Our principal customers in our brand and generic pharmaceutical operations are wholesale drug distributors and major retail drug store chains. These customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of 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 will increase pricing and other competitive pressures on drug manufacturers, including Actavis.

For the year ended December 31, 2012, our two largest customers accounted for 16% and 14%, respectively, of our net revenues. The loss of any of these customers could have a material adverse effect on our business, results of operations, financial condition and cash flows. In addition, none of our customers are party to any long-term supply agreements with us, and thus are able to change suppliers freely should they wish to do so.

***As a result of the Actavis Group acquisition, we may have exposure to additional tax liabilities.***

As a multinational corporation, we are subject to income taxes as well as non-income based taxes, in both the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. Recent proposals by the current U.S. administration for fundamental U.S. international tax reform, including without limitation provisions that would limit the ability of U.S. multinationals to defer U.S. taxes on foreign income, if enacted, could have a significant adverse impact on our effective tax rate following the Actavis Group acquisition.

***As a result of the Actavis Group acquisition, we will be subject to a variety of additional risks that may negatively impact our operations.***

As a result of the Actavis Group acquisition, we will be subject to new and additional risks associated with the business and operations of Actavis. The additional risks we may be exposed to include but are not limited to the following:

tariffs and trade barriers;

regulations related to customs and import/export matters (including sanctions);

longer payment cycles;

tax issues, such as tax law changes and variations in tax laws as compared to the jurisdictions in which we already operate;

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challenges in collecting accounts receivable from customers in the new jurisdictions in which we will operate;

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complying with laws, rules and regulations relating to the manufacturing, marketing, distribution and sale of pharmaceutical products in the new jurisdictions in which we will operate;

operating under regulations in new jurisdictions related to obtaining eligibility for government or private payor reimbursement for our products at the wholesale/retail level;

competition from new local, regional and international competitors;

competing in additional markets where generic products are sold under branded trade names;

cultural and language differences in the new jurisdictions in which we will operate;

complying with additional employment regulations in the new jurisdictions in which we will operate; union workforce negotiations and potential disputes; and

risks related to crimes, strikes, riots, civil disturbances, terrorist attacks and wars in a variety of new geographical locations. We may not be able to adequately address these additional risks. If we are unable to do so, our operations might suffer.

*Our ex-U.S. operations may become less attractive if political and diplomatic relations between the United States and any country where we conduct business operations deteriorates.*

The relationship between the United States and the countries where we conduct business operations may weaken over time. Changes in the state of the relations between any such country and the United States are difficult to predict and could adversely affect our future operations or cause potential target businesses to become less attractive. This could lead to a decline in our profitability. Any meaningful deterioration of the political and diplomatic relations between the United States and the relevant country could have a material adverse effect on our operations.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

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We conduct our operations using a combination of owned and leased properties.

Our owned properties consist of facilities used for R&D, manufacturing, distribution (including warehousing and storage), sales and marketing and administrative functions. The following table provides a summary of locations for our significant owned properties:

<b>Location</b>	<b>Primary Use</b>	<b>Segment</b>
Ag. Varvara, Greece	Manufacturing, R&D, Administration	Actavis Pharma
Auckland, New Zealand	Distribution, Administrative	Actavis Pharma
Barnstaple, UK	Manufacturing, Administration	Actavis Pharma
Bucharest, Romania	Manufacturing, Distribution, Administration	Actavis Pharma
Corona, CA, USA	Manufacturing, Warehouse, Distribution, Administration	Actavis Pharma / Actavis
Davie, FL, USA	Manufacturing, Distribution, R&D, Administration	Specialty Brands Actavis Pharma / Actavis
Dupnitsa, Bulgaria	Manufacturing	Specialty Brands Actavis Pharma
Elizabeth, NJ, USA	Manufacturing, R&D, Administration	Actavis Pharma
Goa, India	Manufacturing	Actavis Pharma
Gurnee, IL, USA	Warehousing, Distribution	Actavis Pharma / Actavis
Hafnarfjordur, Iceland	Manufacturing, Warehousing, Distribution, Administration	Specialty Brands Actavis Pharma
Jakarta-Timur, Indonesia	Manufacturing, Warehousing, Distribution, Administration	Actavis Pharma
Leskovac, Serbia	Manufacturing	Actavis Pharma
Lincolnton, NC, USA	Manufacturing, Administration, Warehouse	Actavis Pharma
Liverpool, UK	Administration, R&D	Actavis Specialty Brands
Mississauga, Canada	Manufacturing, R&D, Administration	Actavis Pharma
Nerviano, Italy	Manufacturing	Actavis Pharma
Podelsk, Russia	Manufacturing	Actavis Pharma
Rio de Janeiro, Brazil	Manufacturing, Distribution, Administration	Actavis Pharma
Troyan, Bulgaria	Manufacturing	Actavis Pharma

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Properties that we lease include R&D, manufacturing, distribution (including warehousing and storage), and administrative facilities. The following table provides a summary of locations for our significant leased properties:

<b>Location</b>	<b>Primary Use</b>	<b>Segment</b>
Belgrade, Serbia	Administration	Actavis Pharma
Birzebbuga, Malta	Manufacturing, Distribution, Administration	Actavis Pharma/Actavis Specialty Brands
Gentofte, Denmark	Administration	Actavis Pharma
Haan, Germany	Distribution	Actavis Pharma
Hafnarfjordur, Iceland	Administration	Actavis Pharma
Istanbul, Turkey	Administration	Actavis Pharma
Kiev, Ukraine	Administration	Actavis Pharma
London, UK	Administration	Actavis Pharma
Lyon, France	Administration	Actavis Pharma
Moscow, Russia	Administration	Actavis Pharma
Mumbai, India	R&D, Administration	Actavis Pharma
Munich, Germany	Administration	Actavis Pharma
Olive Branch, MI, USA	Distribution, Administration	Anda Distribution
Owings Mills, MD, USA	Manufacturing, R&D, Administration	Actavis Pharma
Parsippany, NJ, USA	Administration	Actavis Pharma/Actavis Specialty Brands
Salt Lake City, UT, USA	Manufacturing, Distribution, R&D	Actavis Pharma / Actavis Specialty Brand
Sofia, Bulgaria	Administration	Actavis Pharma
Stockholm, Sweden	Administration	Actavis Pharma
Warsaw, Poland	Administration	Actavis Pharma
Weston, FL, USA	Distribution, Administration, R&D	Actavis Pharma/Anda Distribution
Zejtun, Malta	Manufacturing, Distribution, Administration, R&D	Actavis Pharma

Our leased properties are subject to various lease terms and expirations.

We believe that we have sufficient facilities to conduct our operations during 2013. However, we continue to evaluate the purchase or lease of additional properties, or the consolidation of existing properties as our business requires.

**ITEM 3. LEGAL PROCEEDINGS**

For information regarding legal proceedings, refer to *Legal Matters* in NOTE 18 Commitments and Contingencies in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

**ITEM 4. Not Applicable**

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market for Registrant's Common Equity**

Our common stock was traded on the New York Stock Exchange under the symbol WPI until close of business on January 23, 2013, at which time the symbol was changed to ACT. The following table sets forth the quarterly high and low share trading price information for the periods indicated:

	High	Low
<b>Year ended December 31, 2012:</b>		
First	\$ 67.50	\$ 55.00
Second	\$ 77.73	\$ 65.70
Third	\$ 86.07	\$ 73.39
Fourth	\$ 91.47	\$ 81.73
<b>Year ended December 31, 2011:</b>		
First	\$ 57.52	\$ 50.47
Second	\$ 69.04	\$ 56.13
Third	\$ 73.35	\$ 56.84
Fourth	\$ 72.06	\$ 59.50

As of February 7, 2013, there were approximately 2,295 registered holders of our common stock.

We have not paid any cash dividends since our initial public offering in February 1993, and do not anticipate paying any cash dividends in the foreseeable future.

**Issuer Purchases of Equity Securities**

During the quarter ended December 31, 2012, we repurchased 9,333 shares of our common stock surrendered to the Company to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees as follows:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publically Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
October 1 - 31, 2012	2,464	\$ 85.42		
November 1 - 30, 2012	6,869	\$ 87.83		
December 1 - 31, 2012				

**Recent Sale of Unregistered Securities; Uses of Proceeds from Registered Securities**

None.

**Securities Authorized for Issuance Under Equity Compensation Plans**

For information regarding securities authorized for issuance under equity compensation plans, refer to ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS and NOTE 13 Stockholders Equity in the accompanying Notes to Consolidated Financial Statements in this Annual Report.



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*The information in this section of the Annual Report pertaining to our performance relative to our peers is being furnished but not filed with the SEC, and as such, the information is neither subject to Regulation 14A or 14C or to the liabilities of Section 18 of the Securities Exchange Act of 1934.*

The following graph compares the cumulative 5-year total return of holders of Watson's common stock with the cumulative total returns of the S&P 500 index and the Dow Jones US Pharmaceuticals index. The graph tracks the performance of a \$100 investment in our common stock and in each of the indexes (with reinvestment of all dividends, if any) on December 31, 2007 with relative performance tracked through December 31, 2012.

Notwithstanding anything to the contrary set forth in our previous filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, which might incorporate future filings made by us under those statutes, the following graph will not be deemed incorporated by reference into any future filings made by us under those statutes.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Actavis, Inc., the S&P 500 Index,  
and the Dow Jones US Pharmaceuticals Index

\* \$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

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	12/07	12/08	12/09	12/10	12/11	12/12
<b>Actavis, Inc.</b>	<b>100.00</b>	<b>97.90</b>	<b>145.95</b>	<b>190.31</b>	<b>222.33</b>	<b>316.88</b>
<b>S&amp;P 500</b>	<b>100.00</b>	<b>63.00</b>	<b>79.67</b>	<b>91.67</b>	<b>93.61</b>	<b>108.59</b>
<b>Dow Jones US Pharmaceuticals</b>	<b>100.00</b>	<b>81.85</b>	<b>97.47</b>	<b>99.55</b>	<b>118.11</b>	<b>134.52</b>

*The stock price performance included in this graph is not necessarily indicative of future stock price performance.*



**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA****ACTAVIS, INC.****FINANCIAL HIGHLIGHTS(1)****(In millions, except per share amounts)**

	Years Ended December 31,				
	2012 <sup>(2)</sup>	2011	2010	2009 <sup>(3)</sup>	2008
<b>Operating Highlights:</b>					
Net revenues	\$ 5,914.9	\$ 4,584.4	\$ 3,566.9	\$ 2,793.0	\$ 2,535.5
Operating income(1)	\$ 320.8	\$ 536.2	\$ 305.4	\$ 383.9	\$ 358.2
Net income(1)					
attributable to common shareholders	\$ 97.3	\$ 260.9	\$ 184.4	\$ 222.0	\$ 238.4
Basic earnings per share	\$ 0.77	\$ 2.10	\$ 1.51	\$ 2.11	\$ 2.32
Diluted earnings per share	\$ 0.76	\$ 2.06	\$ 1.48	\$ 1.96	\$ 2.09
<b>Weighted average shares outstanding:</b>					
Basic	125.8	124.5	122.4	105.0	102.8
Diluted	128.4	126.5	124.2	116.4	117.7

	At December 31,				
	2012 <sup>(2)</sup>	2011	2010	2009 <sup>(3)</sup>	2008
<b>Balance Sheet Highlights:</b>					
Current assets	\$ 3,879.7	\$ 2,569.7	\$ 1,786.7	\$ 1,749.2	\$ 1,442.6
Working capital	\$ 1,169.1	\$ 730.2	\$ 978.7	\$ 721.6	\$ 976.4
Total assets	\$ 14,103.5	\$ 6,698.3	\$ 5,686.6	\$ 5,772.4	\$ 3,609.8
Total debt	\$ 6,433.3	\$ 1,033.0	\$ 1,016.1	\$ 1,457.8	\$ 877.9
Total equity	\$ 3,856.4	\$ 3,562.5	\$ 3,282.6	\$ 3,023.1	\$ 2,108.6

- (1) For discussion on comparability of operating income and net income, please refer to financial line item discussion in our Management's Discussion and Analysis of Financial Condition and Results of Operations in this Annual Report.
- (2) On October 31, 2012, the Company completed the acquisition of Actavis Group. The acquisition was consummated for a cash payment of 4.2 billion, or approximately \$5.5 billion, and contingent consideration of up to 5.5 million newly issued shares of Actavis, Inc. common stock or under certain potential conditions, in cash. Actavis Group was privately held generic pharmaceutical company specializing in the development, manufacture and sale of generic pharmaceuticals. Actavis' financial statements included in this report do not include the financial results of the Actavis Group for any of the periods or at any of the dates presented prior to October 31, 2012.
- (3) On December 2, 2009, the Company acquired all the outstanding equity of the Arrow Group in exchange for cash consideration of \$1.05 billion, approximately 16.9 million shares of Restricted Common Stock of Actavis and 200,000 shares of Mandatorily Redeemable Preferred Stock of Actavis and certain contingent consideration. The fair value of the total consideration was approximately \$1.95 billion.

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**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*Except for the historical information contained herein, the following discussion contains forward-looking statements that are subject to known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. We discuss such risks, uncertainties and other factors throughout this report and specifically under the caption*

*Cautionary Note Regarding Forward-Looking Statements under ITEM 1A. RISK FACTORS in this annual report on Form 10-K ( Annual Report ). In addition, the following discussion of financial condition and results of operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report.*

**EXECUTIVE SUMMARY**

**Overview of Actavis**

On January 23, 2013, Watson Pharmaceuticals, Inc. was renamed Actavis, Inc. ( Actavis , the Company , we , us or our ). The Company operates three business segments: Actavis Pharma; Actavis Specialty Brands; and Anda Distribution (also known as Anda ).

Actavis is leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, branded generic, brand, biosimilar and over-the-counter pharmaceutical products. Through its third-party business within the Actavis Pharma segment, Actavis out-licenses generic pharmaceutical products rights developed or acquired by the Company, primarily in Europe. Actavis is also developing biosimilar products within the Actavis Specialty Brands segment. Additionally, we distribute generic and certain select brand pharmaceutical products manufactured by third parties through our Anda Distribution segment. Our largest market is the United States of America ( U.S. ), followed by our key international markets including Europe, Canada, Australia, Southeast Asia, South America and South Africa.

Actavis supports its Actavis Pharma and Actavis Specialty Brands businesses with a significant commitment of approximately 7% of net revenues on product research and development. Our global growth strategy is focused on: (i) internal development of differentiated high-demand products; (ii) establishment of strategic alliances and collaborations that bring new products, technologies and markets to the Company; and (iii) acquisition of products and/or companies that complement our existing portfolio in generics, brands and biosimilars.

As of December 31, 2012, we marketed over 250 generic pharmaceutical product families and over 40 brand pharmaceutical products in the U.S. and a significant number of product families internationally. 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 Anda Distribution segment, we distribute approximately 11,450 stock-keeping units ( SKUs ) in the U.S. primarily to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies) and pharmacy chains, and generic products and certain selective brand products to physicians' offices.

**Acquisitions and Dispositions**

*Acquisition of Actavis Group*

On October 31, 2012, Watson Pharmaceuticals, Inc. completed the acquisition of the Actavis Group. On January 24, 2013, the Company was renamed Actavis, Inc. The acquisition was consummated for a cash payment of 4.2 billion, or approximately \$5.5 billion, and potential contingent consideration payable in the form of up to 5.5 million newly issued shares of Actavis, Inc. common stock or, under certain conditions, in cash. Actavis Group was a privately held generic pharmaceutical company specializing in the development, manufacture and sale of generic pharmaceuticals.

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To finance the purchase of the Actavis Group, we incurred substantial borrowings. For further details, refer to NOTE 10 Long Term Debt in the accompanying Notes to Consolidated Financial Statements in this Annual Report. Actavis will incur greater interest expense than it incurred in prior periods and will be required to dedicate cash flow to servicing its debt. Refer to Liquidity and Capital Resources for further detail.

The Actavis Group acquisition is subject to various risks and uncertainties, including risks relating to the integration of the Actavis Group and risks related to our indebtedness in connection with the acquisition. Refer to Item 1A. Risk Factors.

*Acquisition of Ascent Pharmahealth Limited*

On January 24, 2012, we completed the acquisition of Ascent Pharmahealth Ltd., the Australia and Southeast Asia generic pharmaceutical business of Strides Arcolab Ltd, for AU\$376.6 million in cash, or approximately \$392.6 million, including working capital adjustments. The transaction was funded using cash-on-hand and borrowings from the Company's revolving credit facility. As a result of the acquisition, Actavis enhances its commercial presence in Australia and we gain a selling and marketing capability in Southeast Asia through Ascent's line of branded-generic and over-the-counter products. For additional information on the Ascent acquisition, refer to NOTE 5 Acquisitions and Divestitures.

*Acquisition of Specifar Commercial Industrial Pharmaceutical, Chemical and Construction Exploitations Societe Anonyme (ABEE) ( Specifar )*

On May 25, 2011, Actavis acquired all of the outstanding equity of Paomar PLC ( Paomar ) for cash totaling 398.5 million, or approximately \$559.5 million, including working capital adjustments, and certain contingent consideration (the Specifar Acquisition ). Paomar is a company incorporated under the laws of Cyprus and owner of 100 percent of the shares of Specifar, a company organized under the laws of Greece. Specifar develops, manufactures and markets generic pharmaceuticals. Specifar also out-licenses generic pharmaceutical products, primarily in Europe. Specifar has a commercial presence in the Greek branded generics pharmaceuticals market and owns 100 percent of the shares of Alet Pharmaceuticals Industrial and Commercial Societe Anonyme ( Alet ), a company that markets branded-generic pharmaceutical products in the Greek market. For additional information on the Specifar acquisition, refer to NOTE 5 Acquisitions and Divestitures.

*Product Divestitures*

On October 29, 2012, the Company sold its Rugby over-the-counter ( OTC ) pharmaceutical products and trademarks to The Harvard Drug Group, L.L.C. ( Harvard ) for \$116.6 million. Under the terms of the agreement, Harvard acquired the Rugby trademark and all rights to market, sell and distribute OTC products and nicotine gum products sold under the trademark. The Company retains all rights to manufacture, sell and distribute all store-branded OTC and nicotine gum products, as well as other non-Rugby OTC products in its portfolio. Actavis retains ownership of its nicotine gum Abbreviated New Drug Applications (ANDAs) as well as nicotine gum manufacturing facilities. Also, as part of the transaction, Actavis and Harvard entered into a supply and license agreement under which Actavis manufactures and supplies nicotine gum products sold under the Rugby and Major labels. Major is Harvard's existing private label brand. In connection with the sale of the Rugby assets, the Company recorded a gain of \$88.7 million in other income (expense) in the year ended December 31, 2012.

In order to obtain regulatory approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, in connection with the Actavis Group acquisition, we were required to divest certain assets. In conjunction with the closing of the acquisition, these products were sold to Par Pharmaceuticals Companies, Inc. and Sandoz, Inc.

*Sale of Equity Interest in Moksha8 Pharmaceuticals, Inc. ( Moksha8 )*

On October 22, 2012, the Company sold its investment in Moksha8 for \$46.6 million. Simultaneously, the Company expanded its ongoing sales and marketing collaboration with Moksha8 by granting a license to Moksha8 for five new branded generic products to be developed for the Brazil and Mexico markets in exchange

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for defined milestones and sales royalties. The Company retained generic marketing rights in each market for all products licensed to Moksha8. The Company recorded a gain of \$28.8 million in other income (expense) in the year ended December 31, 2012.

**Biosimilars Collaboration with Amgen**

On December 19, 2011, the Company entered into a collaboration agreement with Amgen, Inc. to develop and commercialize, on a worldwide basis, biosimilar versions of Herceptin<sup>®</sup>, Avastin<sup>®</sup>, Rituxan/Mab Thera<sup>®</sup>, and Erbitux. Under the terms of the agreement, Amgen will assume primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products. The Company will contribute up to \$400.0 million in co-development costs over the course of development, including the provision of development support, and will share product development risks. In addition, we will contribute our significant expertise in the commercialization and marketing of products in highly competitive specialty and generic markets, including helping effectively manage the lifecycle of the biosimilar products. The collaboration products are expected to be sold under a joint Amgen/Actavis label. We will initially receive royalties and sales milestones from product revenues. The collaboration will not pursue biosimilars of Amgen's proprietary products.

On July 13, 2012, the Company entered into a global license agreement with Synthon, obtaining an exclusive license to its trastuzumab molecule, which is being developed as a biosimilar to Herceptin<sup>®</sup>. Actavis subsequently contributed the product to the Company's biosimilar collaboration with Amgen. Under the terms of the Synthon agreement, Amgen and Actavis will assume all responsibility for worldwide development and commercialization of biosimilar trastuzumab, including Phase III clinical trials and global manufacturing. The agreement entitles Synthon to an initial payment and the opportunity to receive a milestone payment and royalties on net sales. Synthon will also receive compensation for transitional support activities provided under the agreement.

*Actavis Pharma Business Development*

The Company's two most significant products in 2012 were the authorized generic version of Concerta<sup>®</sup> (methylphenidate ER) and Lipitor<sup>®</sup> (atorvastatin), which on a combined basis comprised 20.8% of the Company's revenues. These products were sold pursuant to exclusive marketing arrangements.

Methylphenidate ER is sold pursuant to an exclusive agreements with Ortho-McNeil-Janssen Pharmaceuticals, Inc. ( OMJPI ). Under the terms of the agreement, OMJPI supplies the Company with product. Actavis, Inc. launched its authorized generic of Concerta<sup>®</sup> on May 1, 2011. Under the terms of its agreement with OMJPI, the Company pays a royalty to OMJPI based on the gross profit of product revenues as defined in the agreements. During 2012, the royalty payable to OMJPI ranged from 50% to 55% of sales. This royalty includes the cost of the product supplied by OMJPI. Our royalty payable on sales of methylphenidate ER declines when a third party competitor launches a competing bioequivalent product. The change in royalty is a one-time event and is applied on a strength-by-strength basis following the launch of the first third party generic competitor. In January of 2013, a competitor launched a generic version of the 27mg strength, triggering the one time decline in royalty on this strength. Accordingly, for the 27mg strength, commencing in January 2013, the royalty payable to OMJPI will be approximately 30% of sales, which includes the cost of the product supplied by OMJPI. The royalty on the 18mg, 35mg and 54mg strengths will remain at approximately 50% until a competitive launch occurs, at which point the royalty rate will be reduced to approximately 30%. The agreement with OMJPI expires on December 31, 2014 and is subject to normal and customary early termination provisions.

During 2011 and 2012, Atorvastatin was sold pursuant to an exclusive agreement with Pfizer, Inc. ( Pfizer ). Actavis, Inc. launched its authorized generic of Lipitor<sup>®</sup> on November 30, 2011. Due to the significant decline in the market for this product, the Company agreed to terminate this agreement effective January 1, 2013. In exchange, the Company is entitled to receive a royalty on future sales of the product by Pfizer through 2015.

In accordance with the acquisition agreement of the Arrow Group on December 2, 2009, the Arrow Group selling shareholders have the right to receive certain contingent payments based on the after-tax gross profits, as defined by the agreement, on sales of atorvastatin within the U.S. (the Territory ) from product launch date up to and including May 31, 2013 (the Contingent Payment Period ).

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The Company has entered into an agreement with Endo Pharmaceuticals Inc. and Teikoku Seiyaku Co., Ltd to settle all outstanding patent litigation related to the Company's generic version of Lidoderm®. The agreement allows the Company to launch its lidocaine topical patch 5% product on September 15, 2013. The license will be exclusive as to an authorized generic version of Lidoderm® until the earliest of a third party generic launch or seven and one half months after the Company's launch of its generic product. Endo will receive approximately 25% of the gross profit generated on the Company's sales of its generic version of Lidoderm® during the Company's period of exclusivity. On August 23, 2012, the U.S. Food and Drug Administration (FDA) granted final approval of the Company's generic version of Lidoderm®.

Additionally, under the terms of the agreement, the Company's Anda Distribution business will receive and distribute branded Lidoderm® product from Endo each month during the first eight months of 2013 valued up to approximately \$96 million. Actavis' availability of brand product would cease upon the launch of any generic version of Lidoderm®. The receipt of the branded product will be recorded at the time all contingencies related to Actavis' ability to receive and distribute such inventory are resolved.

## **2012 Financial Highlights**

Among the significant consolidated financial highlights for 2012 were the following:

Net revenues grew to \$5,914.9 million from \$4,584.4 million in 2011, an increase of \$1,330.5 million or 29.0%;

Operating income decreased by \$215.4 million or 40.2% to \$320.8 million from \$536.2 million in 2011; and

Net income attributable to common shareholders for 2012 was \$97.3 million (\$0.76 per diluted share) compared to \$260.9 million (\$2.06 per diluted share) in 2011.

## **Segments**

Actavis operates in three segments: Actavis Pharma (previously Global Generics), Actavis Specialty Brands (previously Global Brands) and Anda Distribution (previously Distribution). The Actavis Pharma segment includes off-patent pharmaceutical products that are therapeutically equivalent to proprietary products. The Actavis Specialty Brands segment includes patent-protected products and certain trademarked off-patent products that Actavis sells and markets as brand pharmaceutical products. The Anda Distribution segment mainly distributes generic pharmaceutical products manufactured by third parties, as well as by Actavis, primarily to independent pharmacies, pharmacy chains, pharmacy buying groups and physicians' offices. The Anda Distribution segment operating results exclude sales by Anda of products developed, acquired, or licensed by Actavis' Actavis Pharma and Actavis Specialty Brands segments.

The Company evaluates segment performance based on segment net revenues and segment contribution. Segment contribution represents segment net revenues less cost of sales (excludes amortization), R&D expenses and selling and marketing expenses. The Company does not report total assets, capital expenditures, corporate general and administrative expenses, amortization, gains or losses on asset sales or disposals and impairments by segment as not such information is accounted for at the segment level, nor is such information used by all segments.

**Table of Contents****YEAR ENDED DECEMBER 31, 2012 COMPARED TO 2011**

Results of operations, including segment net revenues, segment operating expenses and segment contribution information for the Company's Actavis Pharma, Actavis Specialty Brands and Anda Distribution segments, consisted of the following (in millions):

	Years Ended December 31,							
	2012			2011				
	Actavis Pharma	Actavis Specialty Brands	Anda Distribution	Total	Actavis Pharma	Actavis Specialty Brands	Anda Distribution	Total
Product sales	\$ 4,385.2	\$ 411.6	\$ 986.4	\$ 5,783.2	\$ 3,320.2	\$ 364.9	\$ 776.2	\$ 4,461.3
Other revenue	60.9	70.8		131.7	47.0	76.1		123.1
Net revenues	4,446.1	482.4	986.4	5,914.9	3,367.2	441.0	776.2	4,584.4
Operating expenses:								
Cost of sales <sup>(1)</sup>	2,428.4	115.4	846.6	3,390.4	1,817.8	94.4	652.7	2,564.9
Research and development	255.6	146.2		401.8	227.7	67.7		295.4
Selling and marketing	281.2	175.5	89.8	546.5	156.0	168.6	77.2	401.8
Contribution	\$ 1,480.9	\$ 45.3	\$ 50.0	\$ 1,576.2	\$ 1,165.7	\$ 110.3	\$ 46.3	\$ 1,322.3
Contribution margin	33.3%	9.4%	5.1%	26.6%	34.6%	25.0%	6.0%	28.8%
General and administrative				624.8				353.1
Amortization				481.1				354.3
Loss on asset sales and impairments, net				149.5				78.7
Operating income				\$ 320.8				\$ 536.2
Operating margin				5.4%				11.7%

(1) Excludes amortization of acquired intangibles including product rights.

**Actavis Pharma Segment***Net Revenues*

Our Actavis Pharma segment develops, manufactures, markets, sells and distributes generic, branded generic and OTC products. Generic products are the therapeutic equivalent to their brand name counterparts and are generally sold at prices significantly less than the brand product. As such, generic products provide an effective and cost-efficient alternative to brand products. When patents or other regulatory exclusivity no longer protect a brand product, or if we are successful in developing a bioequivalent, non-infringing version of a brand product, opportunities exist to introduce off-patent or generic counterparts to the brand product. Additionally, we distribute generic versions of third parties' brand products (sometimes known as Authorized Generics) to the extent such arrangements are complementary to our core business. Our portfolio of generic products includes products we have internally developed, products we have licensed from third parties, and products we distribute for third parties.

Net revenues in our Actavis Pharma segment include product sales and other revenue. Our Actavis Pharma segment product line includes a variety of products and dosage forms. Indications for this line include pregnancy prevention, pain management, depression, hypertension, attention-deficit/hyperactivity disorder and smoking cessation. Dosage forms include oral solids, semi-solids, liquids, gels, transdermals, injectables, inhalation and oral transmucosals.

Other revenues consist primarily of royalties, milestone receipts, commission income and revenue from licensing arrangements.

Net revenues within our Actavis Pharma segment increased 32.0% or \$1,078.9 million to \$4,446.1 million for the year ended December 31, 2012 compared to net revenues of \$3,367.2 million in the prior year. The increase in net revenues was primarily due to higher net revenues as a result of the Actavis Group, Ascent and Specifar acquisitions in October 2012, January 2012 and May 2011, respectively (\$637.9 million),

## Edgar Filing: Actavis, Inc. - Form 10-K

increased unit sales of authorized generic versions of Concerta® (methylphenidate ER) and Lipitor® (atorvastatin) (\$280.2 million), which we launched in May 2011 and November 2011, respectively and increased U.S. unit sales related

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to new products including enoxaparin, progesterone capsules, levalbuteral, vancomycin hydrochloride, metformin hydrochloride extended-release, morphine sulfate extended-release and trospium choride (\$247.2 million). Partially offsetting these increases were price and unit sales declines due to competition including metoprolol, potassium XR and fentanyl transdermal system (\$116.2 million).

### *Cost of Sales*

Cost of sales includes production and packaging costs for the products we manufacture, third party acquisition costs for products manufactured by others, profit-sharing or royalty payments for products sold pursuant to licensing agreements, inventory reserve charges and excess capacity utilization charges, where applicable. Cost of sales does not include amortization costs for acquired product rights or other acquired intangibles.

Cost of sales within our Actavis Pharma segment increased 33.6% or \$610.6 million to \$2,428.4 million for the year ended December 31, 2012 compared to \$1,817.8 million in the prior year due to higher product sales. The increase in cost of sales was primarily due to product costs on atorvastatin, enoxaparin, metformin hydrochlorodine extended-release, progesterone capsules (\$182.5 million) and increased unit sales as a result of the Actavis Group, Ascent and Specifar acquisitions in October 2012, January 2012 and May 2011, respectively (\$406.6 million). Cost of sales as a percentage of net revenues increased to 54.6% from 54.0% in the prior year period primarily related to product mix.

### *Research and Development Expenses*

R&D expenses consist predominantly of personnel-related costs, active pharmaceutical ingredient ( API ) costs, contract research, biostudy and facilities costs associated with product development.

R&D expenses within our Actavis Pharma segment increased 12.3% or \$27.9 million to \$255.6 million for the year ended December 31, 2012 compared to \$227.7 million in the prior year. The increase in R&D expenses was primarily due to higher costs associated with the Actavis Group acquisition.

### *Selling and Marketing Expenses*

Selling and marketing expenses consist mainly of personnel-related costs, distribution costs, professional services costs, insurance, depreciation and travel costs.

Selling and marketing expenses within our Actavis Pharma segment increased 80.3% or \$125.2 million to \$281.2 million for the year ended December 31, 2012 compared to \$156.0 million in the prior year primarily due to higher selling and marketing expenses incurred resulting from the Actavis Group, Ascent and Specifar acquisitions (\$ 112.6 million).

## ***Actavis Specialty Brands Segment***

### *Net Revenues*

Our Actavis Specialty Brands segment includes our key promoted products such as Rapaflo<sup>®</sup>, Gelnique<sup>®</sup>, Crinone<sup>®</sup>, Trelstar<sup>®</sup>, Generess<sup>™</sup> Fe, Androderm<sup>®</sup>, and Kadian<sup>®</sup> and a number of non-promoted products.

Other revenues in the Actavis Specialty Brands segment consist primarily of co-promotion revenue, royalties and the recognition of deferred revenue relating to our obligation to manufacture and supply brand products to third parties. Other revenues also include revenue recognized from R&D and licensing agreements.

Net revenues within our Actavis Specialty Brands segment increased 9.4% or \$41.4 million to \$482.4 million for the year ended December 31, 2012 compared to net revenues of \$441.0 million in the prior year. The increase was due to higher product sales (\$46.7 million) mainly resulting from new products including Generess<sup>®</sup> Fe, sodium ferric gluconate and Kadian<sup>®</sup>, which was acquired as part of the Actavis Group acquisition and key promoted products including Rapaflo<sup>®</sup>, Crinone<sup>®</sup> and INFED<sup>®</sup>. This increase was partially offset by lower sales of certain non-promoted products.



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### *Cost of Sales*

Cost of sales includes production and packaging costs for the products we manufacture, third party acquisition costs for products manufactured by others, profit-sharing or royalty payments for products sold pursuant to licensing agreements, inventory reserve charges and excess capacity utilization charges, where applicable. Cost of sales does not include amortization costs for acquired product rights or other acquired intangibles.

Cost of sales within our Actavis Specialty Brands segment increased 22.2% or \$21.0 million to \$115.4 million for the year ended December 31, 2012 compared to \$94.4 million in the prior year. The increase in cost of sales was due to higher product sales. Cost of sales as a percentage of net revenues increased to 23.9% from 21.4% in the prior year period due to product mix.

### *Research and Development Expenses*

R&D expenses consist mainly of personnel-related costs, contract research costs, clinical and facilities costs associated with the development of our products.

R&D expenses within our Actavis Specialty Brands segment increased 116.0% or \$78.5 million to \$146.2 million for the year ended December 31, 2012 compared to \$67.7 million in the prior year primarily due to an increase in biosimilar product development costs including recombinant follicle stimulating hormone ( rFSH ) and products being developed under our collaboration agreement with Amgen, Inc. (\$59.6 million), higher contractual in-licensing costs (\$13.5 million) and prior year fair value adjustment of certain contingent obligations relating to the acquisition of our progesterone business from Columbia Labs (\$7.7 million), which lowered R&D expenses in the prior year.

### *Selling and Marketing Expenses*

Selling and marketing expenses consist mainly of personnel-related costs, product promotion costs, distribution costs, professional services costs, insurance and depreciation.

Selling and marketing expenses within our Actavis Specialty Brands segment increased 4.1% or \$6.9 million to \$175.5 million for the year ended December 31, 2012 compared to \$168.6 million in the prior year due to higher U.S. field force and support costs (\$7.3 million), primarily related to increased headcount and higher commercial spending in Canada (\$11.2 million) partially offset by lower U.S. product promotional spending (\$11.9 million).

### *Anda Distribution Segment*

#### *Net Revenues*

Our Anda Distribution segment distributes generic and certain select brand pharmaceutical products manufactured by third parties, as well as by Actavis, primarily to independent pharmacies, pharmacy chains, pharmacy buying groups and physicians' offices. Sales are principally generated through an in-house telemarketing staff and through internally developed ordering systems. The Anda Distribution segment operating results exclude sales by Anda of products developed, acquired, or licensed by Actavis' Actavis Pharma and Actavis Specialty Brands segments.

Net revenues within our Anda Distribution segment increased 27.1% or \$210.2 million to \$986.4 million for the year ended December 31, 2012 compared to net revenues of \$776.2 million in the prior year. The increase was primarily due to an increase in third-party new product launches (\$180.4 million) and an increase in U.S. base product sales, which includes volume increases in both generic and branded pharmaceutical product sales offset by price declines (\$29.7 million).

#### *Cost of Sales*

Cost of sales includes third party acquisition costs, profit-sharing or royalty payments for products sold pursuant to licensing agreements and inventory reserve charges, where applicable. Cost of sales does not include amortization costs for acquired product rights or other acquired intangibles.

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Cost of sales within our Anda Distribution segment increased 29.7% or \$193.9 million to \$846.6 million for the year ended December 31, 2012 compared to \$652.7 million in the prior year due to higher product sales. Cost of sales as a percentage of revenue increased to 85.8% compared to 84.1% in the prior year period primarily due to an increase of sales to chain customers at lower than average margins.

*Selling and Marketing Expenses*

Selling and marketing expenses consist mainly of personnel costs, facilities costs, insurance and freight costs which support the Anda Distribution segment sales and marketing functions.

Selling and marketing expenses within our Anda Distribution segment increased 16.3% or \$12.6 million to \$89.8 million for the year ended December 31, 2012 compared to \$77.2 million in the prior year primarily due to higher freight costs (\$6.6 million), higher expenses associated with relocating our Groveport, Ohio distribution operations to the Olive Branch, Mississippi facility (\$3.1 million), and higher sales related expenses (\$2.4 million).

*Corporate General and Administrative Expenses*

(\$ in millions)	Years Ended December 31,		Change	
	2012	2011	Dollars	%
General and administrative expenses	\$ 624.8	\$ 353.1	\$ 271.7	76.9%
<i>as % of net revenues</i>	<i>10.6%</i>	<i>7.7%</i>		

Corporate general and administrative expenses consist mainly of personnel-related costs, facilities costs, insurance, depreciation, litigation and settlement costs and professional services costs which are general in nature and not directly related to specific segment operations.

Corporate general and administrative expenses increased 76.9% or \$271.7 million to \$624.8 million for the year ended December 31, 2012 compared to \$353.1 million in the prior year. The increase was primarily due to higher acquisition, integration and restructuring costs (\$103.1 million), higher litigation charges (\$82.7 million), higher costs resulting from the Actavis Group, Ascent and Specifar acquisitions in October 2012, January 2012 and May 2011, respectively (\$61.1 million), higher legal costs (\$16.3 million), and higher stock-based compensation expenses (\$7.7 million).

*Amortization*

(\$ in millions)	Years Ended December 31,		Change	
	2012	2011	Dollars	%
Amortization	\$ 481.1	\$ 354.3	\$ 126.8	35.8%
<i>as % of net revenues</i>	<i>8.1%</i>	<i>7.7%</i>		

The Company's amortizable assets consist primarily of acquired product rights. Amortization expense for the year ended December 31, 2012 increased as a result of the amortization of atorvastatin and levalbutarol product rights associated with the launch of these products in late 2011 and 2012 (\$40.8 million) and amortization of product rights and other intangible assets acquired in the Actavis Group, Specifar and Ascent acquisitions (\$85.1 million) offset in part by product rights and other intangible assets which were fully amortized subsequent to the prior year period.

*Loss on Asset Sales and Impairments, net*

(\$ in millions)	Years Ended December 31,		Change	
	2012	2011	Dollars	%
Loss on asset sales and impairments, net	\$ 149.5	\$ 78.7	\$ 70.8	90.0%



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Loss on asset sales and impairments for the year ended December 31, 2012 includes a non-cash impairment charge related to product rights and in-process research and development intangible assets acquired in connection with the Specifar acquisition (\$117.8 million), an impairment charge related to a manufacturing facility located in Greece (\$40.3 million), an impairment related to the sale of a German subsidiary (\$17.6 million) and an impairment related to API manufacturing assets in India (\$1.6 million). Partially offsetting these charges was a fair value adjustment of the contingent obligation due to the Specifar selling shareholders based on esomeprazole gross profits (\$27.5 million) and net gains on miscellaneous asset sales (\$0.3 million). The impairment relating to the intangible assets acquired in connection with the Specifar acquisition was recorded during the fourth quarter of 2012 and related to esomeprazole product rights following the Company decision to discontinue selling the product as a result of products acquired in connection with the Actavis Group acquisition (\$16.8 million). In addition, we recorded during the second quarter of 2012 a charge related to three products in development as a result of various factors occurring during the same period mainly related to delays in expected launch dates, competitive factors resulting in realization of lower pricing and incremental costs related to manufacturing efforts. These events led to revised estimates of the fair value of each IPR&D asset compared to the carrying values (\$101.0 million). The impairment for the Greece facility was due to a change in the intended use of the facility as a result of the Company's decision during the third quarter of 2012 to discontinue further construction as a result of the planned acquisition of the Actavis Group.

Loss on assets sales and impairments for the year ended December 31, 2011 included an impairment charge of in-process research and development intangibles assets relating to progesterone gel business acquired from Columbia (\$75.8 million), impairment charges of in-process research and development intangible assets acquired as part of the December 2, 2009 acquisition of the Arrow Group (\$27.0 million), impairment charges related to the sale of our Australia R&D facility and two buildings at our Copiague, New York manufacturing facility (\$14.4 million), an other-than-temporary impairment charges related to equity-method investments (\$9.4 million) and a loss on the sale of an equity method investment (\$2.4 million). These amounts were offset by fair value adjustments of certain contingent obligations relating to the acquisition of our progesterone gel business from Columbia Labs (\$49.0 million) and net gains on the sale of certain assets (\$1.3 million).

**Interest Income**

(\$ in millions)	Years Ended December 31,		Change	
	2012	2011	Dollars	%
Interest income	\$ 2.5	\$ 2.1	\$ 0.4	19.0%

**Interest Expense**

(\$ in millions)	Year Ended December 31,		Change	
	2012	2011	Dollars	%
Interest expense 2009 Senior Notes	\$ 49.3	\$ 49.2	\$ 0.1	
Interest expense 2012 Senior Notes	32.8		32.8	
Interest expense Term Loan	5.9		5.9	
Interest expense Revolving Credit Facility	4.5	0.8	3.7	
Interest expense 2006 Credit Facility		1.1	(1.1)	
Interest expense Mandatorily Redeemable Preferred Stock accretion	16.8	16.7	0.1	
Interest expense Contingent liability accretion	5.2	13.0	(7.8)	
Interest expense Foreign exchange currency option premium payable accretion	0.5		0.5	
Interest expense Other	1.7	1.0	0.7	
Interest expense	\$ 116.7	\$ 81.8	\$ 34.9	42.7%

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Interest expense increased for the year ended December 31, 2012 over the prior year primarily due to interest expense on the Senior Notes issued in connection with the Actavis Group acquisition. For additional information refer to NOTE 10 Long-Term Debt in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

**Other Income (expense)**

(\$ in millions)	Years Ended December 31,		Change	
	2012	2011	Dollars	%
Gain on sale of products	\$ 88.7	\$	\$ 88.7	
Gain on sale of investments	28.8	0.8	28.0	
Gain on sale of divested products	24.0		24.0	
Loss on foreign exchange derivative	(70.4)		(70.4)	
Bridge loan expenses	(37.1)		(37.1)	
Earnings (losses) on equity method investments	1.3	(4.5)	5.8	
Other income	3.2	3.2		
Other income (expense)	\$ 38.5	\$ (0.5)	\$ 39.0	NM

**Gain on Sale of Products**

On October 29, 2012, the Company sold its Rugby over-the-counter ( OTC ) pharmaceutical products and trademarks to The Harvard Drug Group, L.L.C. ( Harvard ) for \$116.6 million. Under the terms of the agreement, Harvard acquired the Rugby trademark and all rights to market, sell and distribute OTC products and nicotine gum products sold under the trademark. The Company retains all rights to manufacture, sell and distribute all store-branded OTC and nicotine gum products, as well as other non-Rugby OTC products in its portfolio. Actavis retains ownership of its nicotine gum Abbreviated New Drug Applications (ANDAs) as well as nicotine gum manufacturing facilities. Also as part of the transaction, Actavis and Harvard entered into a supply and license agreement under which Actavis will manufacture and supply nicotine gum products sold in the Rugby and Major labels. Major is Harvard s existing private label brand. The Company recorded a gain of \$88.7 million in other income (expense), in the fourth quarter of 2012.

**Gain on Sale of Investments**

On October 22, 2012, the Company sold its investment in Moksha8 for \$46.6 million. Simultaneously, Actavis expanded its ongoing sales and marketing collaboration with Moksha8 by granting a license to Moksha8 for five new branded generic products to be developed for the Brazil and Mexico markets in exchange for defined milestones and sales royalties. Actavis will continue to retain generic marketing rights in each market for all products licensed to Moksha8. The Company recorded a gain of \$28.8 million in other income (expense) in the fourth quarter of 2012.

**Gain on Sale of Divested Products**

In order to obtain regulatory approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, in connection with the Actavis Group acquisition, Actavis was required to divest certain assets. On October 31, 2012, these products were sold to Par Pharmaceuticals Companies, Inc. and Sandoz, Inc., which resulted in a gain of \$24.0 million in the fourth quarter of 2012.

**Other Income (loss)**

Included in other income (loss) for the year ended December 31, 2012 is approximately \$70.4 million of realized losses for the derivative instruments entered into to mitigate the exposure resulting from movements of the U.S. dollar against the Euro in connection with the purchase of the Actavis Group and approximately \$37.1 million for the expenses of the bridge loan entered into to fund the purchase of the Actavis Group. These losses

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were partially offset by \$3.0 million contract termination settlement received by an equity method investee and a \$0.8 million gain related to the revaluation of securities issued by an equity method investee.

**Provision for Income Taxes**

(\$ in millions)	Years Ended December 31,		Change	
	2012	2011	Dollars	%
Provision for income taxes	\$ 146.8	\$ 196.9	\$ (50.1)	(25.4)%
Effective tax rate	59.9%	43.2%		

The provision for income taxes differs from the amount computed by applying the statutory U.S. federal income tax rate primarily due to the inability to tax benefit losses incurred in certain foreign jurisdictions and the amortization and impairment of foreign intangibles being tax benefited at rates that are lower than the U.S. federal income tax rate.

The higher effective tax rate for the year ended December 31, 2012, as compared to the prior year period, is primarily a result of additional amortization relating to the Actavis foreign intangibles which is tax benefited at rates lower than the U.S. federal rate. In addition, the effective tax rate for the year ended December 31, 2012 included certain non-recurring items such as an impairment charge being tax benefited at a lower tax rate than the U.S. federal rate and a non deductible loss from a foreign exchange derivative for which no tax benefit was provided. These increases to the effective tax rate were partially offset by the reversal of a deferred tax liability related to the Ascent acquisition.

**YEAR ENDED DECEMBER 31, 2011 COMPARED TO 2010**

Results of operations, including segment net revenues, segment operating expenses and segment contribution information for the Company's Actavis Pharma, Actavis Specialty Brands and Anda Distribution segments, consisted of the following (in millions):

	2011				2010			
	Actavis Pharma	Actavis Specialty Brands	Anda Distribution	Total	Actavis Pharma	Actavis Specialty Brands	Anda Distribution	Total
Product sales	\$ 3,320.2	\$ 364.9	\$ 776.2	\$ 4,461.3	\$ 2,268.9	\$ 316.3	\$ 830.7	\$ 3,415.9
Other revenue	47.0	76.1		123.1	69.5	81.5		151.0
Net revenues	3,367.2	441.0	776.2	4,584.4	2,338.4	397.8	830.7	3,566.9
Operating expenses:								
Cost of sales <sup>(1)</sup>	1,817.8	94.4	652.7	2,564.9	1,198.9	88.4	711.2	1,998.5
Research and development	227.7	67.7		295.4	194.6	101.5		296.1
Selling and marketing	156.0	168.6	77.2	401.8	111.9	137.8	70.3	320.0
Contribution	\$ 1,165.7	\$ 110.3	\$ 46.3	\$ 1,322.3	\$ 833.0	\$ 70.1	\$ 49.2	\$ 952.3
Contribution margin	34.6%	25.0%	6.0%	28.8%	35.6%	17.6%	5.9%	26.7%
General and administrative				353.1				436.1
Amortization				354.3				180.0
Loss on asset sales and impairments, net				78.7				30.8
Operating income								