

Actavis plc  
Form 10-Q  
October 31, 2013

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

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2013**

**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 000-55075**

**ACTAVIS plc**

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

**Ireland**  
**(State or other jurisdiction of**  
**incorporation or organization)**  
**1 Grand Canal Square, Docklands**  
**Dublin 2, Ireland**  
**(Address of principal executive offices, including zip code)**  
**(862) 261-7000**  
**(Registrant's telephone number, including area code)**

**98-1114402**  
**(I.R.S. Employer**  
**Identification Number)**

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  No

Indicate by check mark whether the Registrant (1) 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 submit and post such files). Yes  No

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.

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

\* Effective on October 1, 2013, Actavis plc became the successor registrant to Actavis, Inc. and Warner Chilcott Public Limited Company and will be a "large accelerated filer" in future periodic reports filed pursuant to Section 13 of the Securities Exchange Act of 1934.

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

There were 174,047,953 ordinary shares and 40,000 deferred ordinary shares outstanding as of October 17, 2013.



**TABLE OF CONTENTS**

	<b>PAGE</b>
PART I FINANCIAL INFORMATION	
<u>ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u>	1
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	9
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	13
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	13
PART II OTHER INFORMATION	
<u>ITEM 1. LEGAL PROCEEDINGS</u>	14
<u>ITEM 1A. RISK FACTORS</u>	28
<u>ITEM 6. EXHIBITS</u>	48
<u>SIGNATURES</u>	49

**PART I FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.  
ACTAVIS PLC****CONDENSED CONSOLIDATED BALANCE SHEET**

(Unaudited, in U.S. dollars)

	<b>September 30, 2013</b>
<b>ASSETS</b>	
Current Assets:	
Cash and cash equivalents	\$ 54,101
Total current assets	54,101
Total assets	\$ 54,101
<b>LIABILITIES AND EQUITY</b>	
Total liabilities	\$
Commitments and contingencies	
Equity:	
Ordinary and deferred ordinary shares	53,121
Additional paid-in capital	10
Retained earnings	970
Total equity	54,101
Total liabilities and equity	\$ 54,101

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these consolidated financial statements.

**ACTAVIS PLC****CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**

(Unaudited, in U.S. dollars)

	<b>Three Months Ended September 30, 2013</b>	<b>May 16, 2013 (date of incorporation) to September 30, 2013</b>
Net revenues	\$	\$
Operating (income) expense:		
General and administrative	(970)	(970)
Total operating (income) expense	(970)	(970)
Operating income	970	970
Net income	\$ 970	\$ 970
Earnings per share:		
Ordinary shares Basic & Diluted	\$ 138.51	\$ 138.51
Deferred ordinary shares Basic & Diluted	\$ 0.07	\$ 0.13
Weighted average ordinary shares outstanding:		
Ordinary shares Basic & Diluted	7	7
Deferred ordinary shares Basic & Diluted	13,478	7,381

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these consolidated financial statements.

**ACTAVIS PLC****CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

(Unaudited, in U.S. dollars)

	<b>Three Months Ended September 30, 2013</b>	<b>May 16, 2013 (date of incorporation) to September 30, 2013</b>
Net income	\$ 970	\$ 970
Other comprehensive income		
Comprehensive income	\$ 970	\$ 970

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these consolidated financial statements.

**ACTAVIS PLC****CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS**

(Unaudited, in U.S. dollars)

	<b>May 16, 2013</b> <b>(date of incorporation)</b> <b>to</b> <b>September 30,</b> <b>2013</b>
<b>Cash Flows From Operating Activities:</b>	
Net income	\$ 970
Net cash provided by operating activities	970
<b>Cash Flows From Financing Activities:</b>	
Proceeds from issuance of equity to Matsack	53,131
Net cash provided by financing activities	53,131
Net increase in cash and cash equivalents	54,101
Cash at beginning of period	
Cash at end of period	\$ 54,101

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these consolidated financial statements.



**ACTAVIS PLC**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 General**

Actavis plc (formerly known as Actavis Limited) was incorporated in Ireland on May 16, 2013 as a private limited company and re-registered effective September 18, 2013 as a public limited company. It was established for the purpose of facilitating the business combination between Actavis, Inc. and Warner Chilcott plc ( Warner Chilcott ). As of September 30, 2013, the principal activity of Actavis plc ( Actavis plc , Company or we ) was investment holding. On October 1, 2013, the Company became the successor registrant to Actavis, Inc. and Warner Chilcott in connection with the consummation of the transactions which are further described in Note 5.

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles ( GAAP ) for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted from the accompanying consolidated financial statements. The accompanying interim financial statements are unaudited, but reflect all adjustments which are, in the opinion of management, necessary for a fair statement of Actavis plc s consolidated financial position, results of operations, comprehensive income and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company s results of operations, comprehensive income and cash flows for the interim period are not necessarily indicative of the results of operations, comprehensive income and cash flows that it may achieve in future periods. The consolidated financial statements include the accounts of wholly owned subsidiaries, after elimination of intercompany accounts and transactions, if any.

*Acquisitions of Warner Chilcott and Actavis, Inc.*

On May 19, 2013, the Company entered into a definitive agreement (the Transaction Agreement ) to acquire Warner Chilcott and Actavis, Inc. by means of a scheme of arrangement and merger, as further described in Note 5. The transaction was consummated on October 1, 2013. See Note 5 for more information about the transaction.

Prior to the consummation of the transaction, the following legal entities were formed for the purpose of facilitating the transaction:

Actavis Ireland Holding Limited ( AIHL )

Actavis WC Holding S.à.r.l.

Actavis W.C. Holding Corporation

Actavis W.C. Holding 2 Corporation

Luxembourg Finance S.à.r.l.

*Ordinary and Deferred Shares*

On September 30, 2013, Actavis plc issued 133,628,967 ordinary shares to AIHL, an Irish registered company, in exchange for preference shares. Through a series of transactions the 133,628,967 ordinary shares were ultimately acquired by Actavis W.C. Holding Corporation. As AIHL and Actavis W.C. Holding Corporation are wholly owned subsidiaries, these transactions were eliminated in the consolidated financial statements. In addition, at the balance sheet date, Matsack Nominees Limited ( Matsack ) owned seven ordinary shares and 40,000 deferred ordinary shares which were issued on August 30, 2013. Refer to Note 5 for further information on material events occurring after the balance sheet date.

As of September 30, 2013, there were 1,000,000,000 ordinary shares of \$0.0001 par value per share authorized and seven ordinary shares issued and outstanding at a value of \$0. As of September 30, 2013, there were 40,000 deferred ordinary shares of \$1 par value per share authorized, issued and outstanding at a value of \$53,121.

**NOTE 2 Summary of Significant Accounting Policies**

*Foreign Currency Translation*

The currency of the primary economic environment in which the Company operates ( the functional currency ) is the U.S. dollar. The effects of converting non-functional currency monetary assets and liabilities into the functional currency are recorded as general and administrative expenses in the consolidated statements of operations.

### *Cash and Cash Equivalents*

The Company considers cash and cash equivalents to include cash in banks, cash held in trust, commercial paper and deposits with financial institutions that can be liquidated without prior notice or penalty. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

### *Recent Accounting Pronouncements*

In July 2013, the Financial Accounting Standards Board issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance is not expected to have any impact on the Company's consolidated financial statements.

### **NOTE 3 SHAREHOLDERS EQUITY**

As of September 30, 2013, seven ordinary shares were owned by Matsack with a value of \$0.0007. The holders of the ordinary shares are entitled to dividends, have voting rights and participate pro rata in the total assets of the Company in the event of the Company's winding up.

As of September 30, 2013, the 40,000 deferred ordinary shares of \$1 par value per share issued were owned by Matsack with a value of \$53,121. The holders of the deferred ordinary shares are not entitled to receive dividends or vote. On a return of assets, whether in liquidation or otherwise, the deferred ordinary shares will entitle the holder to the amounts paid up on such shares after the repayment of the capital paid-up on the ordinary shares, plus the payment of \$5,000,000 on each of the ordinary shares and the holders of such deferred ordinary shares (as such) will not be entitled to any further participation in the assets or profits of the Company.

All proceeds from the issuance of shares were used to facilitate the establishment of the Company and its subsidiaries.

On July 18, 2013, Matsack contributed \$10 to the Company recognized as additional paid-in capital.

### **NOTE 4 RELATED PARTY TRANSACTIONS**

As of September 30, 2013, 40,000 was held in trust by Matheson, a related party to Matsack. In addition, refer to Note 3 above for further discussion of the shares held by Matsack.

### **NOTE 5 SUBSEQUENT EVENTS**

On October 1, 2013 (at closing or the Closing Date), pursuant to the Transaction Agreement, dated May 19, 2013, among Actavis, Inc., Warner Chilcott, the Company, Actavis Ireland Holding Limited, Actavis W.C. Holding LLC (now known as Actavis W.C. Holding Inc.) and Actavis W.C. Holding 2 LLC (now known as Actavis W.C. Holding 2 Inc.) (MergerSub), (a) the Company acquired Warner Chilcott (the Acquisition) pursuant to a scheme of arrangement under Section 201, and a capital reduction under Sections 72 and 74, of the Irish Companies Act of 1963 and (b) MergerSub merged with and into Actavis, Inc., with Actavis, Inc. as the surviving corporation in the merger (the Merger) and, together with the Acquisition, the Transactions). Following the consummation of the Transactions, each of Actavis, Inc. and Warner Chilcott became wholly-owned subsidiaries of the Company.

Pursuant to the terms of the Transaction Agreement, each Warner Chilcott ordinary share was converted into 0.160 of a Company ordinary share (the Company Ordinary Shares), and each of Actavis, Inc.'s common shares was converted into one Company Ordinary Share.

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The issuance of the Company Ordinary Shares in connection with the Transactions was registered under the Securities Act of 1933, as amended, pursuant to the Company's registration statement on Form S-4 (File No. 333-189402) filed with the Securities and Exchange Commission and declared effective on July 31, 2013.

Pursuant to Rule 12g-3(c) under the Securities Exchange Act of 1934, as amended (the Exchange Act), the Company is the successor issuer to Actavis, Inc. and to Warner Chilcott. The Company Ordinary Shares are deemed to be registered under Section 12(b) of the Exchange Act, and the Company is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder. The Company Ordinary Shares were approved for listing on the New York Stock Exchange ( NYSE ) and trade under the symbol ACT .

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*Amended and Restated Actavis, Inc. Credit and Guaranty Agreements*

On the Closing Date and pursuant to that certain Term Loan Amendment Agreement (the *Term Amendment Agreement*), by and among Actavis, Inc., Bank of America, N.A. (*BofA*), as administrative agent thereunder, and the lenders party thereto, dated as of August 1, 2013, the Company, as parent guarantor, Actavis WC Holding S.à r.l. (the *ACT Borrower*), as borrower, Actavis, Inc., as a subsidiary guarantor, and BofA, as administrative agent, entered into that certain Amended and Restated Actavis Term Loan Credit and Guaranty Agreement (the *ACT Term Loan Agreement*), dated as of October 1, 2013. The ACT Term Loan Agreement amended and restated Actavis, Inc.'s \$1.8 billion senior unsecured term loan credit facility, dated as of June 22, 2012. At closing, an aggregate principal amount of \$1.6 billion was outstanding under the ACT Term Loan Agreement.

On the Closing Date and pursuant to that certain Revolver Loan Amendment Agreement (the *Revolver Amendment Agreement*) and, together with the Term Amendment Agreement, the *Amendment Agreements*), by and among Actavis, Inc., BofA, as administrative agent thereunder, and the lenders party thereto, dated as of August 1, 2013, the Company, as parent guarantor, the ACT Borrower, as borrower, Actavis, Inc., as a subsidiary guarantor, and BofA, as administrative agent, entered into that certain Amended and Restated Actavis Revolving Credit and Guaranty Agreement (the *ACT Revolving Credit Agreement*) and, together with the ACT Term Loan Agreement, the *Amended and Restated Credit Agreements*), dated as of October 1, 2013. The ACT Revolving Credit Agreement amended and restated Actavis, Inc.'s \$750 million senior unsecured revolving credit facility dated as of September 16, 2011, as amended by that certain Amendment No. 1 to Credit Agreement and Joinder Agreement, dated as of May 21, 2012. At closing, \$6.7 million of letters of credit were outstanding under the ACT Revolving Credit Agreement. At closing, no loans were outstanding under the ACT Revolving Credit Agreement.

*WC Term Loan Credit and Guaranty Agreement*

On the Closing Date, Warner Chilcott Corporation (*WC Corporation*), WC Luxco S.à r.l. (*WC Luxco*), Warner Chilcott Company, LLC (*WC Company*) and, together with WC Corporation and WC Luxco, the *WC Borrowers*), as borrowers, and Warner Chilcott Finance LLC, as a subsidiary guarantor, became parties to that certain WC Term Loan Credit and Guaranty Agreement (the *WC Term Loan Agreement*), dated as of August 1, 2013, by and among the Company, as parent guarantor, BofA, as administrative agent thereunder and a syndicate of banks participating as lenders. Pursuant to the WC Term Loan Agreement, on the Closing Date, the lenders party thereto provided term loans to the WC Borrowers in a total aggregate principal amount of \$2.0 billion, comprised of (i) a tranche pursuant to which loans were made in US Dollars to each of the WC Borrowers in a total aggregate principal amount of \$1.0 billion, which loans will mature on the third anniversary of the Closing Date and (ii) a tranche pursuant to which loans were made in US Dollars to each of the WC Borrowers in a total aggregate principal amount of \$1.0 billion, which loans will mature on the fifth anniversary of the Closing Date. The proceeds of borrowings under the WC Term Loan Agreement were used to finance, in part, the repayment in full of all amounts owing under that certain Credit Agreement, dated as of March 17, 2011, as amended by Amendment No. 1 on August 20, 2012, among Warner Chilcott Holdings Company III, Limited, the WC Borrowers, BofA, as administrative agent thereunder and a syndicate of banks participating as lenders.

*Actavis, Inc. Supplemental Indenture*

On October 1, 2013, the Company, Actavis, Inc. and Wells Fargo Bank, National Association, as trustee, entered into a fourth supplemental indenture (the *Fourth Supplemental Indenture*) to the indenture, dated as of August 24, 2009 (the *Base Indenture*) and, together with the First Supplemental Indenture, the Second Supplemental Indenture and the Third Supplemental Indenture (each as defined below), the *Indenture*), as supplemented by the first supplemental indenture, dated as of August 24, 2009 (the *First Supplemental Indenture*), the second supplemental indenture, dated as of May 7, 2010 (the *Second Supplemental Indenture*), and the third supplemental indenture, dated as of October 2, 2012 (the *Third Supplemental Indenture*). Pursuant to the Fourth Supplemental Indenture, the Company has provided

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a full and unconditional guarantee of Actavis, Inc.'s obligations under its 5.000% Senior Notes due August 15, 2014, (the 2014 Notes), 6.125% Senior Notes due August 15, 2019 (the 2019 Notes), 1.875% Senior Notes due 2017 (the 2017 Notes), 3.250% Senior Notes due 2022 (the 2022 Notes) and 4.625% Senior Notes due 2042 (the 2042 Notes), and together with the 2014 Notes, the 2019 Notes, the 2017 Notes and the 2022 Notes, the Notes).

On October 18, 2013, Actavis, Inc., a wholly-owned subsidiary of the Company, instructed Wells Fargo Bank, National Association, as trustee (the Trustee), pursuant to the Indenture governing its 2014 Notes, to issue a notice from Actavis, Inc. to the holders of the 2014 Notes that Actavis, Inc. has elected to redeem in full the entire aggregate principal amount of the 2014 Notes on November 5, 2013 (the Redemption Date). The 2014 Notes, which have an outstanding principal balance of \$450.0 million and which are fully and unconditionally guaranteed by the Company, will be redeemed at a redemption price equal to the sum of the present values of the remaining scheduled payments of principal and interest on the 2014 Notes from the Redemption Date to August 15, 2014, discounted to the Redemption Date on a semi-annual basis at the Treasury Rate (as defined in the Indenture), plus 40 basis points, plus accrued and unpaid interest, if any, to, but excluding, the Redemption Date.

### *WC Supplemental Indenture*

On October 1, 2013, the Company, WC Company, Warner Chilcott Finance LLC (the Co-Issuer and together with WC Company, the Issuers ) and Wells Fargo Bank, National Association, as trustee (the WC Trustee ), entered into a third supplemental indenture (the Supplemental Indenture ) to the indenture, dated as of August 20, 2010 (the WC Indenture ), among the Issuers, the guarantors party thereto and the WC Trustee, with respect to the Issuers' 7.75% senior notes due 2018 (the WC Notes ). Pursuant to the Supplemental Indenture, the Company has provided a full and unconditional guarantee of the Issuers' obligations under the WC Notes and the WC Indenture.

On October 1, 2013, the Issuers and the Trustee entered into a Release of Guarantees of Certain Guarantors (the Release of Guarantees ), pursuant to which Warner Chilcott's guarantee of the WC Notes was released in accordance with Section 11.05(f) of the WC Indenture and the guarantees of certain other guarantors were released in accordance with Section 11.05(c) or 11.05(e) of the WC Indenture.

### *Indemnification Agreements*

Effective October 1, 2013, the Company entered into deeds of indemnification (the Deeds of Indemnification ) with certain of the Company's directors and officers. The Deeds of Indemnification provide indemnification to such directors and officers to the fullest extent permitted by the laws of Ireland, and in accordance with the Company's Memorandum and Articles of Association, for all expenses actually and reasonably incurred in any action or proceeding in which the officer or director is or may be involved in by reason of the fact that he or she is or was a Company officer or director, on the terms and conditions set forth in the Deeds of Indemnification. Further, the Company agrees to advance expenses incurred in defense of these proceedings, on the terms and conditions set forth in the Deeds of Indemnification. The Deeds of Indemnification also provide procedures for requesting and obtaining indemnification and advancement of expenses.

Effective October 1, 2013, Actavis W.C. Holding Inc. ( U.S. Holdco ), an indirectly wholly-owned subsidiary of the Company, entered into indemnification agreements (the Holdco Indemnification Agreements ) with certain directors and executive officers of the Company. The Holdco Indemnification Agreements provide indemnification to such directors and officers to the fullest extent permitted by the General Corporation Law of Delaware, and in accordance with U.S. Holdco's Bylaws, for all expenses actually and reasonably incurred in any action or proceeding in which the director or officer is or may be involved by reason of the fact that he or she is or was a U.S. Holdco director or officer, on the terms and conditions set forth in the Holdco Indemnification Agreements. Further, U.S. Holdco agrees to advance expenses incurred in defense of these proceedings, on the terms and conditions set forth in the Holdco Indemnification Agreements. The Holdco Indemnification Agreements also provide procedures for requesting and obtaining indemnification and advancement of expenses.

On October 1, 2013, in connection with the consummation of the Transactions, the Company amended and restated its Memorandum and Articles of Association.

### *Other subsequent events*

On October 1, 2013, Matsack transferred legal ownership of their seven Company Ordinary Shares of Actavis plc to Actavis plc and transferred their 40,000 deferred ordinary shares to Actavis, Inc. On the same day, Actavis, Inc. transferred the 40,000 deferred ordinary shares to Watson Pharma International Holding S.à.r.l.

On October 28, 2013, Warner Chilcott Company, LLC ( WCCL ), an indirect wholly-owned subsidiary of the Company, and Sanofi- Aventis U.S. LLC ( Sanofi ) entered into an amendment (the Amendment ) to the global collaboration agreement (as amended, the Collaboration Agreement ) to which WCCL and Sanofi are parties. Under the Collaboration Agreement, about which you may find additional information in the Warner Chilcott plc's Annual

Report on Form 10-K for the year ended December 31, 2012, WCCL and Sanofi co-develop and market Actonel<sup>®</sup> and Atelvia<sup>®</sup> (risedronate sodium) on a global basis, excluding Japan.

Pursuant to the Amendment, the parties amended the Collaboration Agreement with respect to ACTONEL<sup>®</sup> and ATELVIA<sup>®</sup> in the U.S. and Puerto Rico (the Exclusive Territory ) to provide that, in exchange for the payment of a lump sum of \$125.0 million by WCCL to Sanofi no later than December 2, 2013, WCCL's obligations with respect to the global reimbursement payment as it relates to the Exclusive Territory for the year ended December 31, 2014 shall be satisfied in full. The Amendment does not apply to or affect the parties' respective rights and obligations under the Collaboration Agreement with respect to (i) the remainder of 2013 or (ii) territories outside the Exclusive Territory.



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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion of our financial condition and the results of operations should be read in conjunction with the Consolidated Financial Statements and notes thereto included elsewhere in the Quarterly Report on Form 10-Q ( Quarterly Report ). This discussion contains forward-looking statements that are subject to known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially from those expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, among others, those identified under Cautionary Note Regarding Forward-Looking Statements below and elsewhere in this Quarterly Report.

### COMPANY OVERVIEW

Actavis plc (formerly known as Actavis Limited) was incorporated in Ireland on May 16, 2013 as a private limited company and re-registered effective September 18, 2013 as a public limited company. It was established for the purpose of facilitating the acquisition by Actavis, Inc. of Warner Chilcott plc ( Warner Chilcott ). As of September 30, 2013, the principal activity of Actavis plc ( Company or we ) was investment holding.

Through a series of transactions on September 30, 2013, the Company issued 133,628,967 ordinary shares that were ultimately acquired by Actavis W.C. Holding Corporation in exchange for an increased equity interest in Actavis Ireland Holding Limited ( AIHL ), an Irish registered company. As AIHL and Actavis W.C. Holding Corporation are wholly owned subsidiaries, these transactions were eliminated in the consolidated financial statements. In addition, at the balance sheet date, Matsack Nominees Limited ( Matsack ) owned seven ordinary shares with a value of \$0 and 40,000 1 par value deferred ordinary shares with a value of \$53,121.

On October 1, 2013, the Company became the successor registrant to Actavis, Inc. and Warner Chilcott in connection with the consummation of the acquisitions of Warner Chilcott and Actavis, Inc., which is further described below.

### Subsequent Events

#### *Acquisitions of Warner Chilcott and Actavis, Inc.*

On October 1, 2013 (the Closing Date ), we acquired Warner Chilcott (the Acquisition ) pursuant to a scheme of arrangement under Section 201, and a capital reduction under Sections 72 and 74, of the Irish Companies Act of 1963 and our indirect wholly-owned subsidiary merged with and into Actavis, Inc., with Actavis, Inc. as the surviving corporation in the merger (the Merger and, together with the Acquisition, the Transactions ). Following the consummation of the Transactions, each of Actavis, Inc. and Warner Chilcott became wholly-owned subsidiaries of the Company.

In connection with the Transactions, each Warner Chilcott ordinary share was converted into 0.160 of a Company ordinary share (the Company Ordinary Shares ), and each of Actavis, Inc.'s common shares was converted into one Company Ordinary Share.

The issuance of the Company Ordinary Shares in connection with the Transactions was registered under the Securities Act of 1933, as amended, pursuant to the Company's registration statement on Form S-4 (File No. 333-189402) filed with the SEC and declared effective on July 31, 2013.

Pursuant to Rule 12g-3(c) under the Exchange Act, the Company is the successor issuer to Actavis, Inc. and to Warner Chilcott. The Company Ordinary Shares are deemed to be registered under Section 12(b) of the Exchange Act, and the Company is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder. The Company Ordinary Shares were approved for listing on the New York Stock Exchange ( NYSE ) and

trade under the symbol ACT .

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*Financing Related to the Acquisitions*

The Company satisfied the cash components of the Transactions (*i.e.*, cash payments required under the Warner Chilcott Equity Award Holder Proposal as defined in the Transaction Agreement) and paid certain transactional expenses on the Closing Date of the Acquisition with cash on hand of the Company, Actavis, Inc. and/or Warner Chilcott and drawings under available credit facilities. However, the consummation of the Acquisition was not conditioned upon the receipt of any financing.

*Amended and Restated Actavis, Inc. Credit and Guaranty Agreements*

Actavis, Inc. entered into (i) that certain Term Loan Amendment Agreement (the *Term Loan Amendment Agreement*) by and among Actavis, Inc., Bank of America, N.A. (*BofA*), as administrative agent thereunder, and the lenders party thereto and (ii) that certain Revolver Loan Amendment Agreement (the *Revolver Amendment Agreement* and, together with the Term Amendment Agreement, the *Amendment Agreements*), by and among Actavis, Inc., BofA, as administrative agent thereunder, and the lenders party thereto, each dated as of August 1, 2013. The Amendment Agreements amended and restated (i) Actavis, Inc.'s \$1.8 billion senior unsecured term loan credit facility, dated as of June 22, 2012 (such facility, prior to its amendment and restatement pursuant to the Term Amendment Agreement, the *Existing Term Loan*), and (ii) Actavis, Inc.'s \$750.0 million senior unsecured revolving credit facility, dated as of September 2011, as amended by that certain Amendment No. 1 to Credit Agreement and Joinder Agreement, dated as of May 21, 2012 (such facility, prior to its amendment and restatement pursuant to the Revolver Amendment Agreement, the *Existing Revolver*).

On the Closing Date and pursuant to the Amendment Agreements, the Company, as parent guarantor, Actavis WC Holding S.à r.l. (*the ACT Borrower*), as borrower, Actavis, Inc., as a subsidiary guarantor, and BofA, as administrative agent thereunder, entered into that certain Amended and Restated Actavis Term Loan Credit and Guaranty Agreement (the *ACT Term Loan Agreement*) and that certain Amended and Restated Revolving Credit and Guaranty Agreement (the *ACT Revolving Credit Agreement*), each dated as of October 1, 2013. The Existing Term Loan and the Existing Revolver, as amended by the Amendment Agreements, are referred to herein collectively as the *Amended and Restated Credit Facilities*. The Amendment Agreements, among other things: (i) replaced Actavis, Inc., as borrower, with the ACT Borrower, (ii) added the Company and Actavis, Inc. as guarantors, (iii) deleted the springing minimum net worth financial maintenance covenant and (iv) revised certain representations and warranties, financial reporting requirements and other affirmative and negative covenants and events of default, as more fully set out in the Amended and Restated Credit Facilities. In addition, the Revolver Amendment extended the maturity of the Existing Revolver by one year, to September 16, 2017 (or if such day is not a business day, the next preceding business day).

The effectiveness of the Amended and Restated Credit Facilities on the Closing Date of the Acquisition was subject to several conditions, including (i) no Warner Chilcott Material Adverse Effect under the Transaction Agreement, (ii) consummation of the Acquisition, (iii) receipt of customary closing documents and (iv) other customary closing conditions, as more fully set out in the Amended and Restated Credit Facilities. At closing, an aggregate principal amount of \$1.6 billion was outstanding under the ACT Term Loan Agreement, and \$6.7 million of letters of credit were outstanding under the ACT Revolving Credit Agreement. At closing, no loans were outstanding under the ACT Revolving Credit Agreement.

*WC Term Loan Credit and Guaranty Agreement*

The Company, as parent guarantor, BofA, as administrative agent thereunder, and a syndicate of banks participating as lenders entered into that certain WC Term Loan Credit and Guaranty Agreement (the *WC Term Loan Agreement*), dated as of August 1, 2013, and on the Closing Date, Warner Chilcott Corporation (*WC Corporation*), WC Luxco S.à r.l. (*WC Luxco*), Warner Chilcott Company, LLC (*WC Company*) and, together with WC Corporation and WC Luxco,

the WC Borrowers ), as borrowers, and Warner Chilcott Finance LLC, as a subsidiary guarantor, became parties to the WC Term Loan Agreement. Pursuant to the WC Term Loan Agreement, on the Closing Date, the lenders party thereto provided term loans to the WC Borrowers in a total aggregate principal amount of \$2.0 billion, comprised of (i) a tranche pursuant to which loans were made in US Dollars to each of the WC Borrowers in a total aggregate principal amount of \$1.0 billion, which loans will mature on the third anniversary of the Closing Date and (ii) a tranche pursuant to which loans were made in US Dollars to each of the WC Borrowers in a total aggregate principal amount of \$1.0 billion, which loans will mature on the fifth anniversary of the Closing Date. The proceeds of borrowings under the WC Term Loan Agreement were used to finance, in part, the repayment in full of all amounts owing under that certain Credit Agreement, dated as of March 17, 2011, as amended by Amendment No. 1 on August 20, 2012, among Warner Chilcott Holdings Company III, Limited, the WC Borrowers, BofA, as administrative agent thereunder and a syndicate of banks participating as lenders.

Borrowings under the WC Term Loan Agreement are subject to conditions that are substantially similar to those in the Amended and Restated Credit Facilities, and the final termination date for the availability of the loans under the WC Term Loan Agreement is the End Date under the Transaction Agreement.

*Actavis, Inc. Supplemental Indenture*

On the Closing Date, the Company, Actavis, Inc. and Wells Fargo Bank, National Association, as trustee, entered into a fourth supplemental indenture to the indenture, dated as of August 24, 2009 pursuant to which the Company has provided a full and unconditional guarantee of Actavis, Inc.'s obligations under its 5.000% Senior Notes due August 15, 2014, (the 2014 Notes ), 6.125% Senior Notes due August 15, 2019, 1.875% Senior Notes due 2017, 3.250% Senior Notes due 2022 and 4.625% Senior Notes due 2042.

On October 18, 2013, Actavis, Inc. instructed Wells Fargo Bank, National Association, as trustee (the Trustee ), pursuant to the indenture governing its 2014 Notes, to issue a notice from Actavis, Inc. to the holders of the 2014 Notes that Actavis, Inc. has elected to redeem in full the entire aggregate principal amount of the 2014 Notes on November 5, 2013 (the Redemption Date ). The 2014 Notes, which have an outstanding principal balance of \$450.0 million and which are fully and unconditionally guaranteed by the Company, will be redeemed at a redemption price equal to the sum of the present values of the remaining scheduled payments of principal and interest on the 2014 Notes from the Redemption Date to August 15, 2014, discounted to the Redemption Date on a semi-annual basis at the Treasury Rate (as defined in the Indenture), plus 40 basis points, plus accrued and unpaid interest, if any, to, but excluding, the Redemption Date.

*WC Supplemental Indenture*

On the Closing Date, the Company, WC Company, Warner Chilcott Finance LLC (the Co-Issuer and together with WC Company, the Issuers ) and Wells Fargo Bank, National Association, as trustee (the WC Trustee ), entered into a third supplemental indenture (the Supplemental Indenture ) to the indenture, dated as of August 20, 2010 (the WC Indenture ), with respect to the Issuers' 7.75% senior notes due 2018 (the WC Notes ) pursuant to which, the Company has provided a full and unconditional guarantee of the Issuers' obligations under the WC Notes and the WC Indenture.

On the Closing Date, the Issuers and the WC Trustee also entered into a Release of Guarantees of Certain Guarantors, pursuant to which Warner Chilcott's guarantee of the WC Notes and the guarantees of certain other guarantors were released in accordance with the terms of the WC Indenture.

*Indemnification Agreements and Other Events*

Effective as of the Closing Date, the Company entered into deeds of indemnification (the Deeds of Indemnification ) with certain of the Company's directors and officers. The Deeds of Indemnification provide indemnification to such directors and officers to the fullest extent permitted by the laws of Ireland, and in accordance with the Company's Memorandum and Articles of Association, for all expenses actually and reasonably incurred in any action or proceeding in which the officer or director is or may be involved in by reason of the fact that he or she is or was a Company officer or director, on the terms and conditions set forth in the Deeds of Indemnification. Further, the Company agrees to advance expenses incurred in defense of these proceedings, on the terms and conditions set forth in the Deeds of Indemnification. The Deeds of Indemnification also provide procedures for requesting and obtaining indemnification and advancement of expenses.

Effective as of the Closing Date, Actavis W.C. Holding Inc. ( U.S. Holdco ), an indirectly wholly-owned subsidiary of the Company, entered into indemnification agreements (the Holdco Indemnification Agreements ) with certain directors and executive officers of the Company. The Holdco Indemnification Agreements provide indemnification to such directors and officers to the fullest extent permitted by the General Corporation Law of Delaware, and in accordance with U.S. Holdco's Bylaws, for all expenses actually and reasonably incurred in any action or proceeding in which the director or officer is or may be involved by reason of the fact that he or she is or was a U.S. Holdco director or officer, on the terms and conditions set forth in the Holdco Indemnification Agreements. Further, U.S. Holdco agrees to advance expenses incurred in defense of these proceedings, on the terms and conditions set forth in

the Holdco Indemnification Agreements. The Holdco Indemnification Agreements also provide procedures for requesting and obtaining indemnification and advancement of expenses.

On October 1, 2013, in connection with the consummation of the Transactions, the Company amended and restated its memorandum and articles of association.

*Other subsequent events*

On October 1, 2013, Matsack transferred legal ownership of their seven Company Ordinary Shares of Actavis plc to Actavis plc and transferred their 40,000 deferred ordinary shares to Actavis, Inc. On the same day, Actavis, Inc. transferred the 40,000 deferred ordinary shares to Watson Pharma International Holding S.à.r.L.

On October 28, 2013, Warner Chilcott Company, LLC ( WCCL ), an indirect wholly-owned subsidiary of the Company, and Sanofi- Aventis U.S. LLC ( Sanofi ) entered into an amendment (the Amendment ) to the global collaboration agreement (as amended, the Collaboration Agreement ) to which WCCL and Sanofi are parties. Under the Collaboration Agreement, about which you may find additional information in the Warner Chilcott plc s Annual Report on Form 10-K for the year ended December 31, 2012, WCCL and Sanofi co-develop and market Actonel<sup>®</sup> and Atelvia<sup>®</sup> (risedronate sodium) on a global basis, excluding Japan.

Pursuant to the Amendment, the parties amended the Collaboration Agreement with respect to ACTONEL<sup>®</sup> and ATELVIA<sup>®</sup> in the U.S. and Puerto Rico (the Exclusive Territory ) to provide that, in exchange for the payment of a lump sum of \$125.0 million by WCCL to Sanofi no later than December 2, 2013, WCCL s obligations with respect to the global reimbursement payment as it relates to the Exclusive Territory for the year ended December 31, 2014 shall be satisfied in full. The Amendment does not apply to or affect the parties respective rights and obligations under the Collaboration Agreement with respect to (i) the remainder of 2013 or (ii) territories outside the Exclusive Territory.

## **Results of Operations**

### *General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2013 and for the period from May 16, 2013 (date of incorporation) to September 30, 2013 were \$970 consisting of foreign exchange gains related to foreign denominated cash and cash equivalents.

## **Liquidity and Capital Resources**

Working capital at September 30, 2013 was \$54,101 of cash and cash equivalents.

### *Cash Flows from Operating Activities*

Operating cash flows for the period from May 16, 2013 (date of incorporation) to September 30, 2013 consist of \$970 of foreign exchange gains related to foreign denominated cash and cash equivalents.

### *Cash Flows from Financing Activities*

Financing cash flows during the period from May 16, 2013 (date of incorporation) to September 30, 2013 were \$53,131, consisting of proceeds from the issuance of equity to Matsack

### *Off-Balance Sheet Arrangements*

At September 30, 2013 we do not have any material off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, liquidity or capital resources.

### *Recent Accounting Pronouncements*

In July 2013, the Financial Accounting Standards Board issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance is not expected to have any impact on the Company s consolidated financial statements.





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## 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 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 or other variations 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 **Item 1A. Risk Factors**, and other risks and uncertainties detailed herein and from time to time in our filings with the Securities and Exchange Commission (the "SEC"), 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.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Disclosure under this Item 3 has been omitted in accordance with the Instructions to Paragraph 305(c) of Item 305, Regulation S-K.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Limitations on Effectiveness of Controls and Procedures**

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls

and procedures were effective at the reasonable assurance level as of September 30, 2013.

- 13 -

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## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

Actavis and its affiliates are involved in various disputes, governmental and/or regulatory inspections, inquiries, investigations and proceedings, and litigation matters that arise from time to time in the ordinary course of business. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect the Company, its results of operations, financial condition and cash flows. The Company's general practice is to expense legal fees as services are rendered in connection with legal matters, and to accrue for liabilities when losses are probable and reasonably estimable.

We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that is accrued.

Our legal proceedings range from cases brought by a single plaintiff to mass tort actions and class actions with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims (including, but not limited to, *qui tam* actions, antitrust, product liability, breach of contract, securities, patent infringement and trade practices), some of which present novel factual allegations and/or unique legal theories. In addition, a number of the matters pending against us are at very early stages of the legal process (which in complex proceedings of the sort faced by us often extend for several years). As a result, some matters have not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable us to estimate a range of possible loss. In those proceedings in which plaintiffs do request publicly quantified amounts of relief, we do not believe that the quantified amounts are meaningful because they are merely stated jurisdictional limits, exaggerated and/or unsupported by the evidence or applicable burdens of proof.

#### Antitrust Litigation

*AndroGel*<sup>®</sup> *Litigation*. On January 29, 2009, the U.S. Federal Trade Commission and the State of California filed a lawsuit in the United States District Court for the Central District of California (*Federal Trade Commission, et. al. v. Watson Pharmaceuticals, Inc., et. al., USDC Case No. CV 09-00598*) alleging that the September 2006 patent lawsuit settlement between Watson Pharmaceuticals, Inc. (Watson now known as Actavis, Inc.) and Solvay Pharmaceuticals, Inc., related to AndroGel<sup>®</sup> 1% (testosterone gel) CIII is unlawful. The complaint generally alleged that Watson improperly delayed its launch of a generic version of AndroGel<sup>®</sup> in exchange for Solvay's agreement to permit Watson to co-promote AndroGel<sup>®</sup> for consideration in excess of the fair value of the services provided by Watson, in violation of federal and state antitrust and consumer protection laws. The complaint sought equitable relief and civil penalties. On February 2 and 3, 2009, three separate lawsuits alleging similar claims were filed in the United States District Court for the Central District of California by various private plaintiffs purporting to represent certain classes of similarly situated claimants (*Meijer, Inc., et. al., v. Unimed Pharmaceuticals, Inc., et. al., USDC Case No. EDCV 09-0215*); (*Rochester Drug Co-Operative, Inc. v. Unimed Pharmaceuticals Inc., et. al., Case No. EDCV 09-0226*); (*Louisiana Wholesale Drug Co. Inc. v. Unimed Pharmaceuticals Inc., et. al, Case No. EDCV 09-0228*). On April 8, 2009, the Court transferred the government and private cases to the United States District Court for the Northern District of Georgia. On April 21, 2009 the State of California voluntarily dismissed its lawsuit against Watson without prejudice. The Federal Trade Commission and the private plaintiffs in the Northern District of Georgia filed amended complaints on May 28, 2009. The private plaintiffs amended their complaints to include allegations concerning conduct before the U.S. Patent and Trademark Office, conduct in connection with the listing of Solvay's patent in the Food and Drug Administration's (FDA) Orange Book, and sham litigation. Additional actions alleging similar claims have been filed in various courts by other private plaintiffs purporting to represent certain classes of similarly situated direct or indirect purchasers of AndroGel<sup>®</sup> (*Stephen L. LaFrance Pharm., Inc. d/b/a SAJ Dist. v. Unimed Pharms., Inc., et. al., D. NJ Civ. No. 09-1507*); (*Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund v.*

*Unimed Pharms. Inc., et al.*, D. NJ Civ. No. 09-1856); (*Scurto v. Unimed Pharms., Inc., et al.*, D. NJ Civ. No. 09-1900); (*United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund v. Unimed Pharms., Inc., et al.*, D. MN Civ. No. 09-1168); (*Rite Aid Corp. et al. v. Unimed Pharms., Inc. et al.*, M.D. PA Civ. No. 09-1153); (*Walgreen Co., et al. v. Unimed Pharms., LLC, et al.*, MD. PA Civ. No. 09-1240); (*Supervalu, Inc. v. Unimed Pharms., LLC, et al.*, ND. GA Civ. No. 10-1024); (*LeGrand v. Unimed Pharms., Inc., et al.*, ND. GA Civ. No. 10-2883); (*Jabo's Pharmacy Inc. v. Solvay Pharmaceuticals, Inc., et al.*, Cocke County, TN Circuit Court Case No. 31,837). On April 20, 2009, Watson was dismissed without prejudice from the *Stephen L. LaFrance* action pending in the District of New Jersey. On October 5, 2009, the Judicial Panel on Multidistrict Litigation transferred all actions then pending outside of the United States District Court for the Northern District of Georgia to that district for consolidated pre-trial proceedings (*In re: AndroGel® Antitrust Litigation (No. II)*, MDL Docket No. 2084), and all currently-pending related actions are presently before that court. On February 22, 2010, the judge presiding over all the consolidated litigations related to AndroGel® then pending in the United States District Court for the Northern District of Georgia granted Watson's motions to dismiss the complaints, except the portion of the private plaintiffs complaints that include allegations concerning sham litigation. Final judgment in favor of the defendants was entered in the Federal Trade Commission's action on April 21, 2010. On April 25, 2012, the Court of Appeals affirmed the dismissal. On June 17, 2013, the Supreme Court issued a decision, holding that the settlements between brand and generic drug companies which include a payment from the brand company

to the generic competitor must be evaluated under a rule of reason standard of review and ordered the case remanded. On July 20, 2010, the plaintiff in the *Fraternal Order of Police* action filed an amended complaint adding allegations concerning conduct before the U.S. Patent and Trademark Office, conduct in connection with the listing of Solvay's patent in the Food and Drug Administration's Orange Book, and sham litigation similar to the claims raised in the direct purchaser actions. On October 28, 2010, the judge presiding over MDL 2084 entered an order pursuant to which the *LeGrand* action, filed on September 10, 2010, was consolidated for pretrial purposes with the other indirect purchaser class action as part of MDL 2084 and made subject to the Court's February 22, 2010 order on the motion to dismiss. In February 2012, the direct and indirect purchaser plaintiffs and the defendants filed cross-motions for summary judgment, and on June 22, 2012, the indirect purchaser plaintiffs, including Fraternal Order of Police, *LeGrand* and HealthNet, filed a motion for leave to amend and consolidate their complaints. On September 28, 2012, the district court granted summary judgment in favor of the defendants on all outstanding claims. The plaintiffs then appealed. On September 12 and 13, 2013, respectively, the indirect purchaser plaintiffs and direct purchaser plaintiffs filed motions with the district court, asking the court for an indicative ruling that it would vacate its final order on the parties' summary judgment motions and conduct further proceedings in light of the Supreme Court's ruling in the *Federal Trade Commission* action, should the Court of Appeals remand the case to the district court. On October 23, 2013, the district court granted the motions.

The Company believes that these actions are without merit and intends to defend itself vigorously. However, these actions, if successful, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Cipro*<sup>®</sup> *Litigation*. Beginning in July 2000, a number of suits were filed against Watson and certain Company affiliates including The Rugby Group, Inc. (Rugby) in various state and federal courts alleging claims under various federal and state competition and consumer protection laws. Several plaintiffs have filed amended complaints and motions seeking class certification. Approximately 42 cases were filed against Watson, Rugby and other Company entities. Many of these actions have been dismissed. Actions remain pending in various state courts, including California, Kansas, Tennessee, and Florida. The actions generally allege that the defendants engaged in unlawful, anticompetitive conduct in connection with alleged agreements, entered into prior to Watson's acquisition of Rugby from Sanofi Aventis (Sanofi), related to the development, manufacture and sale of the drug substance ciprofloxacin hydrochloride, the generic version of Bayer's brand drug, Cipro<sup>®</sup>. The actions generally seek declaratory judgment, damages, injunctive relief, restitution and other relief on behalf of certain purported classes of individuals and other entities. The action pending in Kansas, which the court previously terminated administratively, has been reopened. There has been no action in the cases pending in Florida and Tennessee since 2003. In the action pending in the California Superior Court for the County of San Diego (*In re: Cipro Cases I & II, JCCP Proceeding Nos. 4154 & 4220*), on July 21, 2004, the California Court of Appeal ruled that the majority of the plaintiffs would be permitted to pursue their claims as a class. On August 31, 2009, the California Superior Court granted defendants' motion for summary judgment, and final judgment was entered on September 24, 2009. On October 31, 2011, the California Court of Appeal affirmed the Superior Court's judgment. On December 13, 2011, the plaintiffs filed a petition for review in the California Supreme Court. On February 15, 2012, the California Supreme Court granted review. On September 12, 2012, the California Supreme Court entered a stay of all proceedings in the case pending a decision from the United States Supreme Court in an unrelated case that raises similar legal issues. The California Supreme Court lifted the stay on June 26, 2013 following the ruling by the United States Supreme Court. Plaintiffs and Bayer recently announced that they have reached an agreement to settle the claims pending against Bayer. Plaintiffs are continuing to pursue claims against the generic defendants, including Watson and Rugby. The remaining parties now will resume briefing in this appeal.

In addition to the pending actions, the Company understands that various state and federal agencies are investigating the allegations made in these actions. Sanofi has agreed to defend and indemnify Watson and its affiliates in connection with the claims and investigations arising from the conduct and agreements allegedly undertaken by Rugby and its affiliates prior to Watson's acquisition of Rugby, and is currently controlling the defense of these

actions.

*Doryx Litigation.* In July 2012, Mylan Pharmaceuticals Inc. (Mylan) filed a complaint against Warner Chilcott plc (Warner Chilcott) and Mayne Pharma International Pty. Ltd. (Mayne) in the U.S. District Court for the Eastern District of Pennsylvania alleging that Warner Chilcott and Mayne prevented or delayed Mylan's generic competition to Warner Chilcott's DORYX products in violation of U.S. federal antitrust laws and tortiously interfered with Mylan's prospective economic relationships under Pennsylvania state law. (*Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Co., et al.*, E.D.Pa. No. 12-cv-03824). In the complaint, Mylan seeks unspecified treble and punitive damages and attorneys' fees.

Following the filing of Mylan's complaint, three putative class actions were filed against Warner Chilcott and Mayne by purported direct purchasers, and one putative class action was filed against Warner Chilcott and Mayne by purported indirect purchasers, each in the same court. In each case the plaintiffs allege that they paid higher prices for Warner Chilcott's DORYX products as a result of Warner Chilcott's and Mayne's alleged actions preventing or delaying generic competition in violation of U.S. federal antitrust laws and/or state laws. Plaintiffs seek unspecified injunctive relief, treble damages and/or attorneys' fees. The court consolidated the purported class actions and the action filed by Mylan and ordered that all the pending cases proceed on the same schedule.

On February 5, 2013, four retailers, including HEB Grocery, Safeway, Inc., Supervalu, Inc. and Walgreen Co., filed in the same court a civil antitrust complaint in their individual capacities against Warner Chilcott and Mayne regarding DORYX. (*Walgreen Co., Safeway, Inc., Supervalu, Inc. and HEB Grocery Co, LP. v. Warner Chilcott Public Limited Co., et al.*, E.D.Pa. No. 13-cv-00658). On March 28, 2013, another retailer, Rite Aid, filed a similar complaint in the same court. (*Rite Aid Corp. v. Warner Chilcott Public Limited Co., et al.*, E.D.Pa. No. 13-cv-01644). Both retailer complaints recite similar facts and assert similar legal claims for relief to those asserted in the related cases described above. Both retailer complaints have been consolidated with the cases described above.

Warner Chilcott and Mayne moved to dismiss the claims of Mylan, the direct purchasers, the indirect purchasers and the retailers. On November 21, 2012, the Federal Trade Commission filed with the court an amicus curiae brief supporting the plaintiffs' theory of relief. On June 12, 2013, the court entered a denial, without prejudice, of Warner Chilcott and Mayne's motions to dismiss. Discovery is ongoing in the consolidated cases. Plaintiffs' motions for class certification remain pending before the court, with no class having yet been certified.

The Company intends to vigorously defend its rights in the litigations. However, it is impossible to predict with certainty the outcome of any litigation, and the Company can offer no assurance as to when the lawsuits will be decided, whether the Company will be successful in its defense and whether any additional similar suits will be filed. The plaintiffs collectively seek approximately \$1.2 billion in compensatory damages. The Company believes these amounts are unfounded and without merit. However, any award of compensatory damages could be subject to trebling. If these claims are successful such claims could adversely affect the Company and could have a material adverse effect on the Company's business, financial condition, results of operation and cash flows. An estimate of the potential loss, or range of loss, if any, to the Company relating to these proceedings is not possible at this time.

*Loestrin 24<sup>®</sup> Litigation.* On April 5, 2013, two putative class actions were filed in the federal district court (*New York Hotel Trades Council & Hotel Assoc. of New York City, Inc. Health Benefits Fund v. Warner Chilcott Pub. Ltd. Co., et al.*, D.N.J., Civ. No. 13-02178, and *United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund v. Warner Chilcott (US), LLC, et al.*, E.D.Pa., No. 13-01807) against Actavis, Inc. and certain affiliates alleging that Watson's 2009 patent lawsuit settlement with Warner Chilcott related to Loestrin 24<sup>®</sup> (norethindrone acetate/ethinyl estradiol tablets and ferrous fumarate tablets, Loestrin 24<sup>®</sup>) is unlawful. The complaints, both asserted on behalf of putative classes of end-payors, generally allege that Watson and another generic manufacturer improperly delayed launching generic versions of Loestrin 24<sup>®</sup> in exchange for substantial payments from Warner Chilcott, which at the time was an unrelated company, in violation of federal and state antitrust and consumer protection laws. The complaints each seek declaratory and injunctive relief and damages. On April 15, 2013, the plaintiff in *New York Hotel Trades* withdrew its complaint and, on April 16, 2013, refiled it in the federal court for the Eastern District of Pennsylvania (*New York Hotel Trades Council & Hotel Assoc. of New York City, Inc. Health Benefits Fund v. Warner Chilcott Public Ltd. Co., et al.*, E.D.Pa., Civ. No. 13-02000). Additional complaints have been filed by different plaintiffs seeking to represent the same putative class of end-payors (*A.F. of L. A.G.C. Building Trades Welfare Plan v. Warner Chilcott, et al.*, D.N.J. 13-02456, *Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund v. Warner Chilcott Public Ltd. Co., et al.*, E.D.Pa. Civ. No. 13-02014), *Electrical Workers 242 and 294 Health & Welfare Fund v. Warner Chilcott Public Ltd. Co., et al.*, E.D.Pa. Civ. No. 13-2862 and *City of Providence v. Warner Chilcott Public Ltd. Co., et al.*, D.R.I. Civ. No. 13-307). In addition to the end-payor suits, two lawsuits have been filed on behalf of a class of direct payors (*American Sales Company, LLC v. Warner Chilcott Public Ltd., Co. et al.*, D.R.I. Civ. No. 12-347 and *Rochester Drug Co-Operative Inc., v. Warner Chilcott (US), LLC, et al.*, E.D.Pa. Civ. No. 13-133476). On June 18, 2013, defendants filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) to consolidate these cases in one federal district court. After a hearing on September 26, 2013, the JPML issued an order conditionally transferring all related Loestrin 24 cases to the federal court for the District of Rhode Island. A preliminary hearing is scheduled for November 4, 2013. The consolidated case is still in its early stages and discovery has not yet begun on either the class allegations or merits. The Company anticipates additional claims or lawsuits based on the same or similar allegations.

The Company believes that these actions are without merit and intends to defend both its brand and generic defendant entities vigorously. However, these actions, if successful, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Paroxetine Investigation.* On April 19, 2013, the Office of Fair Trading issued a Statement of Objections against GlaxoSmithKline ( GSK ) and various generic drug companies, including Actavis UK Limited, formerly known as Alpharma Limited, now a subsidiary of the Company, alleging that GSK's settlements with such generic drug companies improperly delayed generic entry of paroxetine, in violation of the United Kingdom's competition laws. The Company has not yet responded to the Statement of Objections but believes it has substantial meritorious defenses to the allegations. However, an adverse determination in the matter could have an adverse effect on the Company's business, results of operations, financial condition and cash flows.



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**Commercial Litigation**

*Fax Litigation Medical West Ballas Pharmacy, LTD, et al. v. Anda, Inc.*, (Circuit Court of the County of St. Louis, State of Missouri, Case No. 08SL-CC00257). In January 2008, Medical West Ballas Pharmacy, LTD, filed a putative class action complaint against Anda, Inc. alleging conversion and alleged violations of the Telephone Consumer Protection Act ( TCPA ) and Missouri Consumer Fraud and Deceptive Business Practices Act. In April 2008, plaintiff filed an amended complaint substituting Anda, Inc., a subsidiary of the Company, as the defendant. The amended complaint alleges that by sending unsolicited facsimile advertisements, Anda misappropriated the class members paper, toner, ink and employee time when they received the alleged unsolicited faxes, and that the alleged unsolicited facsimile advertisements were sent to the plaintiff in violation of the TCPA and Missouri Consumer Fraud and Deceptive Business Practices Act. The TCPA allows recovery of minimum statutory damages of \$500 per violation, which can be trebled if the violations are found to be willful. The complaint seeks to assert class action claims on behalf of the plaintiff and other similarly situated third parties. In April 2008, Anda filed an answer to the amended complaint, denying the allegations. In November 2009, the court granted plaintiff's motion to expand the proposed class of plaintiffs from individuals for which Anda lacked evidence of express permission or an established business relationship to All persons who on or after four years prior to the filing of this action, were sent telephone facsimile messages advertising pharmaceutical drugs and products by or on behalf of Defendant. In November 2010, the plaintiff filed a second amended complaint further expanding the definition and scope of the proposed class of plaintiffs. On December 2, 2010, Anda filed a motion to dismiss claims the plaintiff is seeking to assert on behalf of putative class members who expressly consented or agreed to receive faxes from Defendant, or in the alternative, to stay the court proceedings pending resolution of Anda's petition to the FCC (discussed below). On April 11, 2011, the court denied the motion. On May 19, 2011, the plaintiff's filed their motion seeking certification of a class of entities with Missouri telephone numbers who were sent Anda faxes for the period January 2004 through January 2008. The motion has been briefed. However, the court granted Anda's motion to vacate the class certification hearing until similar issues are resolved in either or both the pending *Nack* litigation or with the FCC Petition, both of which are described in more detail below. A status conference is currently scheduled for November 13, 2013. No trial date has been set in the matter.

On May 1, 2012, an additional action under the TCPA was filed by Physicians Healthsource, Inc., purportedly on behalf of the end users of the fax numbers in the United States but outside Missouri to which faxes advertising pharmaceutical products for sale by Anda were sent. (*Physicians Healthsource Inc. v. Anda Inc.* United States District Court for the Southern District of Florida, 12 CV 60798). On July 10, 2012, Anda filed its answer and affirmative defenses. The matter is in its preliminary stages and no trial date has been set.

Several issues raised in plaintiff's motion for class certification in the *Medical West* matter were addressed by the Eighth Circuit Court of Appeals in an unrelated case to which Anda is not a party, *Nack v. Walburg*, No. 11-1460. *Nack* concerned whether there is a private right of action for failing to include any opt-out notice on faxes sent with express permission, contrary to a Federal Communications Commission (FCC) Regulation that requires such notice on fax advertisements. The Eighth Circuit granted Anda leave to file an *amicus* brief and to participate during oral argument in the matter, which was held on September 19, 2012. In its ruling, issued May 21, 2013, the Eighth Circuit held that *Nack*'s arguments on appeal amounted to challenges to the FCC's regulation and that the court lacked jurisdiction to entertain such challenges pursuant to the Hobbs Act and it would otherwise not decide any similar challenges without the benefit of full participation by the FCC.

In a related matter, on November 30, 2010, Anda filed a petition with the FCC, asking the FCC to clarify the statutory basis for its regulation requiring opt-out language on faxes sent with express permission of the recipient (the FCC Petition ). On May 2, 2012, the Consumer & Governmental Affairs Bureau of the FCC dismissed the FCC Petition. On May 14, 2012, Anda filed an application for review of the Bureau's dismissal by the full Commission, requesting the FCC to vacate the dismissal and grant the relief sought in the FCC Petition. The FCC has not ruled on the application for review. Anda believes it has substantial meritorious defenses to the putative class actions brought under the TCPA,

including but not limited to its receipt of consent to receive facsimile advertisements from many of the putative class members, and intends to defend the actions vigorously. However, these actions, if successful, could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Columbia Laboratories, Inc. Securities Litigation.* On June 8, 2012, Watson and certain of its officers were named as defendants in a consolidated amended class action complaint filed in the United States District Court for the District of New Jersey (*In re: Columbia Laboratories, Inc. Securities Litigation*, Case No. CV 12-614) by a putative class of Columbia Laboratories' stock purchasers. The amended complaint generally alleges that between December 6, 2010 and January 20, 2012, Watson and certain of its officers, as well as Columbia Laboratories and certain of its officers, made false and misleading statements regarding the likelihood of Columbia Laboratories obtaining FDA approval of Prochieve® progesterone gel, Columbia Laboratories' developmental drug for prevention of preterm birth. Watson licensed the rights to Prochieve® from Columbia Laboratories in July 2010. The amended complaint further alleges that the defendants failed to disclose material information concerning the statistical analysis of the clinical studies performed by Columbia Laboratories in connection with its pursuit of FDA approval of Prochieve®. The complaint seeks

unspecified damages. On August 14, 2012, the defendants filed a motion to dismiss all of the claims in the amended complaint, which the court granted on June 11, 2013. Plaintiffs filed a second amended complaint on July 11, 2013. Defendants filed motions to dismiss the second amended complaint on August 9, 2013. On October 21, 2013, the court granted the motion to dismiss the second amended complaint. In ruling on the motion to dismiss, the court also ruled that if the plaintiffs seek to further amend the complaint, they must file a motion within thirty days seeking permission to do so. The Company believes the case is without merit and that it has substantial meritorious defenses, which it intends to vigorously pursue. Additionally, the Company maintains insurance to provide coverage for the claims alleged in the action. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. The action, if successful, or if insurance does not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Omeprazole Delayed-release Capsules (Generic version of Prilosec®)*. In July 1999, Astra Aktiebolag, Aktiebolaget Hassle, Astra Merck Enterprises Inc. and Astra Merck Inc. (collectively Astra) sued Andrx Pharmaceuticals (Andrx) (which the Company acquired in 2006) in the United States District Court for the Southern District of Florida, alleging that sales of Andrx's omeprazole capsules, a generic version of Astra's Prilosec would infringe certain U.S. Patents, including U.S. Patent Nos. 4,786,505 (the 505 patent) and 4,853,230 (the 230 patent) (*Astra Aktiebolag et al. v. Andrx Pharmaceuticals Inc., Case No. 99cv6893*). The complaint sought injunctive relief. This case was then consolidated by the Multi-District Litigation Panel and transferred to the United States District Court for the Southern District of New York. On October 30, 2002, the District Court entered Final Judgment that the Andrx products would infringe certain claims of the 505 patent and the 230 patent and that Andrx was enjoined from commercializing its product prior to April 20, 2007. On December 11, 2003, the United States Court of Appeals for the Federal Circuit affirmed the District Court decision. On February 8, 2010, Astra filed a supplemental complaint in the District Court alleging that in 2001 Andrx manufactured its generic omeprazole capsules in preparation for a launch in the event of a favorable District Court decision. Astra's supplemental complaint sought damages for that manufacture. On July 12, 2013, the District Court scheduled a jury trial beginning September 30, 2013 on the potential damages in connection with Andrx's manufacture (but not sale) of its generic omeprazole capsules. On September 20, 2013 the Court granted Andrx's motion to exclude the testimony of Astra's only expert witness (Daubert Motion). On September 30, 2013, the Court entered a Consent Judgment in favor of Andrx, which states [b]ecause Astra has concluded that it cannot meet its burden to prove damages in this case in view of the Court's grant of Andrx's Daubert Motion, Astra requests that the Court grant judgment as a matter of law in favor of Andrx, and award Astra no damages. The Court grants that request and thus enters judgment. Astra has indicated that it will appeal. The Company believes it has substantial meritorious defenses to the case and intends to vigorously defend against the damage claim. However, if Astra's action is successful, a damages award could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*West Virginia Prescription Drug Abuse Litigation*. On June 26, 2012, the State of West Virginia filed a lawsuit against multiple distributors of prescription drugs, including Andax, Inc., a subsidiary of the Company (*State of West Virginia v. Amerisourcebergen Drug Corporation, et. al., Boone County Circuit Court Civil Case No. 12-C-141*). The complaint generally alleges that the defendants distributed prescription drugs in West Virginia in violation of state statutes, regulation and common law. The complaint seeks injunctive relief and unspecified damages and penalties. On July 26, 2012, a co-defendant removed the case to the federal court for the Southern District of West Virginia. On March 27, 2013, the court granted plaintiff's motion to remand the case to state court. The case is in its preliminary stages and the Company believes it has substantial meritorious defenses to the claims alleged. However, an adverse determination in the case could have an adverse effect on the Company's business, results of operations, financial condition and cash flows.

### **FDA Litigation**

In May 2002, Company subsidiary Watson Laboratories, Inc. reached an agreement with the FDA on the terms of a consent decree with respect to its Corona, California manufacturing facility. The court approved the consent decree on May 13, 2002 (*United States of America v. Watson Laboratories, Inc., et. al.*, United States District Court for the Central District of California, EDCV-02-412-VAP). The consent decree applies only to the Company's Corona, California facility and not other manufacturing sites. The decree requires that the Corona, California facility complies with the FDA's current Good Manufacturing Practices (cGMP) regulations.

Pursuant to the agreement, the Company hired an independent expert to conduct inspections of the Corona facility at least once each year. In each year from 2002 through 2012, the independent expert has reported its opinion to the FDA that, based on the findings of the audit of the facility, the FDA's applicable cGMP requirements, applicable FDA regulatory guidance, and the collective knowledge, education, qualifications and experience of the expert's auditors and reviewers, the systems at the Corona facility audited and evaluated by the expert are in compliance with the FDA's cGMP regulations. However, the FDA is not required to accept or agree with the independent expert's opinion. The FDA has conducted periodic inspections of the Corona facility since the entry of the

consent decree, and concluded its most recent general cGMP inspection in November 2012. At the conclusion of the inspection, the FDA inspectors issued a Form 483 to the facility identifying certain observations concerning the instances where the facility failed to follow cGMP regulations. The facility has responded to the Form 483 observations and has provided the FDA with a corrective action plan to address the observations noted in the Form 483. On April 19, 2013, the independent expert concluded its annual inspection of the Corona, California facility. The independent expert confirmed the types of observations identified by the FDA during its November 2012 inspection, and reported its observations to the FDA in May 2013. During the inspection, the independent expert verified that certain actions in the corrective action plan had been made. The independent expert has agreed to continue to evaluate the corrective actions being taken and to re-inspect the facility during the second half of 2013, and to further evaluate at that time the facility's compliance with FDA's cGMP regulations. In September 2013, the FDA requested an update on the actions taken by the Company to correct the violations noted at the conclusion of the November 2012 inspection. The Company has responded to the FDA and has provided the requested information. In October 2013 the independent expert conducted a follow up review and verified that certain corrective actions have been completed in conformance with the updates provided by the Company. If in the future, the FDA determines that, with respect to its Corona facility, the Company has failed to comply with the consent decree or FDA regulations, including cGMPs, or has failed to adequately address the FDA's inspectional observations, the consent decree allows the FDA to order a variety of actions to remedy the deficiencies. These actions could include ceasing manufacturing and related operations at the Corona facility, and recalling affected products. Such actions, if taken by the FDA, could have a material adverse effect on the Company, its results of operations, financial position and cash flows.

## **Patent Litigation**

### **Patent Enforcement Matters**

*Actonel Once-a-Month.* In August 2008, December 2008 and January 2009, Procter & Gamble's global branded pharmaceutical business ( PGP ) and Hoffman-La Roche Inc. ( Roche ) received Paragraph IV certification notice letters from Teva Pharmaceutical Industries, Ltd. (together with its subsidiaries Teva ), Sun Pharma Global, Inc. ( Sun ) and Apotex Inc. and Apotex Corp. (together Apotex ), indicating that each such company had submitted to the FDA an Abbreviated New Drug Application ( ANDA ) seeking approval to manufacture and sell generic versions of the ACTONEL 150 mg product ( ACTONEL OaM ). The notice letters contended that Roche's U.S. Patent No. 7,192,938 (the 938 Patent ), a method patent expiring in November 2023 (including a 6-month pediatric extension of regulatory exclusivity) which Roche licensed to PGP with respect to ACTONEL OaM, was invalid, unenforceable or not infringed. PGP and Roche filed patent infringement suits against Teva in September 2008 (*Procter & Gamble Co. et al. v. Teva Pharms. USA, Inc.*, Case No. 08-cv-627), Sun in January 2009 (*Procter & Gamble Co. et al. v. Sun Pharma Global, Inc.*, Case No. 09-cv-061) and Apotex in March 2009 (*Procter & Gamble Co. et al. v. Apotex Inc. et al.*, Case No. 09-cv-143) in the U.S. District Court for the District of Delaware charging each with infringement of the 938 Patent. The lawsuits resulted in a stay of FDA approval of each defendant's ANDA for 30 months from the date of PGP's and Roche's receipt of notice, subject to the prior resolution of the matters before the court. The stay of approval of each of Teva's, Sun's and Apotex's ANDAs has expired, and the FDA has tentatively approved Teva's ANDA with respect to ACTONEL OaM. However, none of the defendants challenged the validity of the underlying U.S. Patent No. 5,583,122 (the 122 Patent ), which covers all of the ACTONEL products, including ACTONEL OaM, and does not expire until June 2014 (including a 6-month pediatric extension of regulatory exclusivity). As a result, the Company does not believe that any of the defendants will be permitted to market their proposed generic versions of ACTONEL OaM prior to June 2014.

On February 24, 2010, Warner Chilcott and Roche received a Paragraph IV certification notice letter from Mylan indicating that it had submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of ACTONEL OaM. The notice letter contends that the 938 Patent, which expires in November 2023 and covers ACTONEL OaM, is invalid and/or will not be infringed. Warner Chilcott and Roche filed a patent suit against Mylan in April 2010 in the U.S. District Court for the District of Delaware charging Mylan with infringement of the 938

Patent based on its proposed generic version of ACTONEL OaM (*Procter & Gamble Co. et al. v. Mylan Pharms. Inc.*, Case No. 10-cv-285). The lawsuit resulted in a stay of FDA approval of Mylan's ANDA for 30 months from the date of Warner Chilcott's and Roche's receipt of notice, subject to prior resolution of the matter before the court. The stay of approval of Mylan's ANDA has now expired. Since Mylan did not challenge the validity of the underlying '122 Patent, which expires in June 2014 (including a 6-month pediatric extension of regulatory exclusivity) and covers all of the ACTONEL products, the Company does not believe that Mylan will be permitted to market its proposed ANDA product prior to the June 2014 expiration of the '122 Patent (including a 6-month pediatric extension of regulatory exclusivity).

In October, November and December 2010 and February 2011, Warner Chilcott and Roche received Paragraph IV certification notice letters from Sun, Apotex, Teva and Mylan, respectively, indicating that each such company had amended its existing ANDA covering generic versions of ACTONEL OaM to include a Paragraph IV certification with respect to Roche's U.S. Patent No. 7,718,634 (the '634 Patent'). The notice letters contended that the '634 Patent, a method patent expiring in November 2023 (including a 6-month pediatric extension of regulatory exclusivity) which Roche licensed to Warner Chilcott with respect to

ACTONEL OaM, was invalid, unenforceable or not infringed. Warner Chilcott and Roche filed patent infringement suits against Sun and Apotex in December 2010, against Teva in January 2011 and against Mylan in March 2011 in the U.S. District Court for the District of Delaware charging each with infringement of the 634 Patent. The Company believes that no additional 30-month stay is available in these matters because the 634 Patent was listed in the FDA's Orange Book subsequent to the date on which Sun, Apotex, Teva and Mylan filed their respective ANDAs with respect to ACTONEL OaM. However, the underlying 122 Patent, which covers all of the ACTONEL products, including ACTONEL OaM, does not expire until June 2014 (including a 6-month pediatric extension of regulatory exclusivity).

Warner Chilcott and Roche's actions against Teva, Apotex, Sun and Mylan for infringement of the 938 Patent and the 634 Patent arising from each such party's proposed generic version of ACTONEL OaM were consolidated for all pretrial purposes (in Case No. 08-cv-627), and a consolidated trial for those suits was previously expected to be held in July 2012. Following an adverse ruling in Roche's separate ongoing patent infringement suit before the U.S. District Court for the District of New Jersey relating to its Boniva® product, in which the court held that claims of the 634 Patent covering a monthly dosing regimen using ibandronate were invalid as obvious, Teva, Apotex, Sun and Mylan filed a motion for summary judgment in Warner Chilcott's ACTONEL OaM patent infringement litigation. In the motion, the defendants have sought to invalidate the asserted claims of the 938 Patent and 634 Patent, which cover a monthly dosing regimen using risedronate, on similar grounds. The previously scheduled trial has been postponed pending resolution of the new summary judgment motion. A hearing on Teva, Apotex, Sun and Mylan's motions for summary judgment of invalidity and a separate motion by Warner Chilcott and Roche for summary judgment of infringement took place on December 14, 2012.

To the extent that any ANDA filer also submitted a Paragraph IV certification with respect to U.S. Patent No. 6,165,513 covering ACTONEL OaM, Warner Chilcott has determined not to pursue an infringement action with respect to this patent. While Warner Chilcott and Roche intend to vigorously defend the 938 Patent and the 634 Patent and protect their legal rights, the Company can offer no assurance as to when the lawsuits will be decided, whether the lawsuits will be successful or that a generic equivalent of ACTONEL OaM will not be approved and enter the market prior to the expiration of the 938 Patent and the 634 Patent in 2023 (including, in each case, a 6-month pediatric extension of regulatory exclusivity).

*Asacol HD.* In September 2011, Warner Chilcott received a Paragraph IV certification notice letter from Zydus Pharmaceuticals USA, Inc. (together with its affiliates, Zydus) indicating that Zydus had submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of Warner Chilcott's ASACOL 800 mg product (ASACOL HD). Zydus contends that Warner Chilcott's U.S. Patent No. 6,893,662, expiring in November 2021 (the 662 Patent), is invalid and/or not infringed. In addition, Zydus indicated that it had submitted a Paragraph III certification with respect to Medeva Pharma Suisse AG's (Medeva) U.S. Patent No. 5,541,170 (the 170 Patent) and U.S. Patent No. 5,541,171 (the 171 Patent), formulation and method patents which the Company exclusively licenses from Medeva covering Warner Chilcott's ASACOL products, consenting to the delay of FDA approval of the ANDA product until the 170 Patent and the 171 Patent expire in July 2013. In November 2011, Warner Chilcott filed a lawsuit against Zydus in the U.S. District Court for the District of Delaware charging Zydus with infringement of the 662 Patent (*Warner Chilcott Co., LLC v. Zydus Pharms. (USA) Inc. et al.*, Case No. 1:2011cv01105). The lawsuit results in a stay of FDA approval of Zydus' ANDA for 30 months from the date of Warner Chilcott's receipt of the Zydus notice letter, subject to prior resolution of the matter before the court. While the Company intends to vigorously defend the 662 Patent and pursue its legal rights, the Company can offer no assurance as to when the pending litigation will be decided, whether the lawsuit will be successful or that a generic equivalent of ASACOL HD will not be approved and enter the market prior to the expiration of the 662 Patent in 2021.

*Atelvia.* In August and October 2011 and March 2012, Warner Chilcott received Paragraph IV certification notice letters from Watson Laboratories, Inc. Florida (together with Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.) and its subsidiaries, Actavis), Teva and Ranbaxy Laboratories Ltd. (together with its affiliates, Ranbaxy) indicating

that each had submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of ATELVIA 35 mg tablets ( ATELVIA ). The notice letters contend that Warner Chilcott's U.S. Patent Nos. 7,645,459 (the 459 Patent ) and 7,645,460 (the 460 Patent ), two formulation and method patents expiring in January 2028, are invalid, unenforceable and/or not infringed. Warner Chilcott filed a lawsuit against Actavis in October 2011 (*Warner Chilcott Co., LLC et al. v. Watson Pharms., Inc. et al.*, Case No. 11-cv-5989), against Teva in November 2011 (*Warner Chilcott Co., LLC et al. v. Teva Pharms. USA, Inc. et al.*, Case No. 11-cv-6936) and against Ranbaxy in April 2012 (*Warner Chilcott Co., LLC et al. v. Ranbaxy, Inc. et al.*, Case No. 12-cv-2474) in the U.S. District Court for the District of New Jersey charging each with infringement of the 459 Patent and 460 Patent. On August 21, 2012, the United States Patent and Trademark Office issued to the Company U.S. Patent No. 8,246,989 (the 989 Patent ), a formulation patent expiring in January 2026. The Company listed the 989 Patent in the FDA's Orange Book, each of Actavis, Teva and Ranbaxy amended its Paragraph IV certification notice letter to contend that the 989 Patent is invalid and/or not infringed, and Warner Chilcott amended its complaints against Actavis, Teva and Ranbaxy to assert the 989 Patent. The lawsuits result in a stay of FDA approval of each defendant's ANDA for 30 months from the date of Warner Chilcott's receipt of such defendant's original notice letter, subject to prior resolution of the matter before the court. The Company does not believe that the amendment of its complaints against Actavis, Teva



and Ranbaxy to assert the '989 Patent will result in any additional 30-month stay. In addition, none of the ANDA filers certified against the '122 Patent, which covers all of the ACTONEL and ATELVIA products and expires in June 2014 (including a 6-month pediatric extension of regulatory exclusivity). On October 2, 2013, Actavis divested its ANDA to Amneal Pharmaceuticals. No trial date has been set.

While the Company intends to vigorously defend the '459 Patent, the '460 Patent and the '989 Patent and pursue its legal rights, the Company can offer no assurance as to when the lawsuits will be decided, whether such lawsuits will be successful or that a generic equivalent of ATELVIA will not be approved and enter the market prior to the expiration of the '989 Patent in 2026 and/or the '459 Patent and the '460 Patent in 2028.

*Generess® Fe.* On November 22, 2011, Warner Chilcott Company sued Mylan Inc., Mylan Pharmaceuticals Inc. and Famy Care Ltd. in the United States District Court for the District of New Jersey, alleging that sales of norethindrone and ethinyl estradiol and ferrous fumarate tablets, a generic version of Warner Chilcott's Generess® Fe tablets (which is exclusively licensed by Warner Chilcott), would infringe U.S. Patent No. 6,667,050 (the '050 patent) (*Warner Chilcott Company LLC v. Mylan Inc., et al., Case No. 11cv6844*). The complaint seeks injunctive relief. On December 12, 2011 Warner Chilcott sued Lupin Ltd. and Lupin Pharmaceuticals, Inc. in the United States District Court for the District of New Jersey, alleging that sales of Lupin's generic version of Generess® Fe would infringe the '050 patent. (*Warner Chilcott Company LLC v. Lupin Ltd., et al., Case No. 11cv7228*). The complaint seeks injunctive relief. Warner Chilcott's lawsuits against Mylan and Lupin have been consolidated and remain pending. Pursuant to the provisions of the Hatch-Waxman Act, the FDA is precluded from granting final approval to the generic applicants until the earlier of thirty months after the generic applicant provided Warner Chilcott with notice of its abbreviated new drug application filing or the generic applicant prevails in the pending litigation. The trial is scheduled to begin on January 13, 2014. The Company believes Warner Chilcott has meritorious claims to prevent the generic applicants from launching a generic version of Generess Fe. However, if a generic applicant prevails in the pending litigation or launches a generic version of Generess Fe before the pending litigation is finally resolved, it could have an adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Lo Loestrin FE.* In July 2011 and April 2012, Warner Chilcott received Paragraph IV certification notice letters from Lupin and Actavis indicating that each had submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of Warner Chilcott's oral contraceptive, LO LOESTRIN FE. The notice letters contend that the '394 Patent and Warner Chilcott's U.S. Patent No. 7,704,984 (the '984 Patent), which cover LO LOESTRIN FE and expire in 2014 and 2029, respectively, are invalid and/or not infringed. Warner Chilcott filed a lawsuit against Lupin in September 2011 (*Warner Chilcott Co., LLC v. Lupin Ltd. et al., Case No. 11-cv-5048*) and against Actavis in May 2012 (*Warner Chilcott Co., LLC v. Watson Labs., Inc. et al., Case No. 12-cv-2928*) in the U.S. District Court for the District of New Jersey charging each with infringement of the '394 Patent and the '984 Patent. Warner Chilcott granted Lupin and Actavis covenants not to sue on the '394 Patent with regard to their ANDAs seeking approval for a generic version of LO LOESTRIN FE, and the court dismissed all claims concerning the '394 Patent in the Lupin and the Actavis litigations in December 2012 and February 2013, respectively. The lawsuits result in a stay of FDA approval of each defendant's ANDA for 30 months from the date of Warner Chilcott's receipt of such defendant's notice letter, subject to the prior resolution of the matter before the court. On October 2, 2013, Actavis divested its ANDA to Amneal Pharmaceuticals. On October 4, 2013, Amneal Pharmaceuticals was substituted for Actavis as a defendant. A joint trial began on October 7, 2013 and concluded on October 17, 2013. The Court has not issued its decision.

While the Company intends to vigorously defend the '984 Patent and pursue its legal rights, it can offer no assurance as to when the lawsuits will be decided, whether such lawsuits will be successful or that a generic equivalent of LO LOESTRIN FE will not be approved and enter the market prior to the expiration of the '984 Patent in 2029.

*Patent Defense Matters*

*Bayer Patent Litigation.* In August 2012, Bayer Pharma AG (together with its affiliates, Bayer ) filed a complaint against Warner Chilcott in the U.S. District Court for the District of Delaware alleging that Warner Chilcott s manufacture, use, offer for sale, and/or sale of its LO LOESTRIN FE oral contraceptive product infringes Bayer s U.S. Patent No. 5,980,940 (*Bayer Intellectual Property GMBH et al. v. Warner Chilcott Co., LLC et al.*, Case No. 12-cv-1032). In the complaint, Bayer seeks injunctive relief and unspecified monetary damages for the alleged infringement. In December 2012, Bayer amended the complaint to add a patent interference claim seeking to invalidate the Company s 984 Patent, which covers the LO LOESTRIN FE product.

On February 19, 2013, Bayer filed a complaint against the Company in the U.S. District Court for the District of Nevada alleging that Warner Chilcott s LOESTRIN 24 FE oral contraceptive product infringes Bayer s U.S. Patent No. RE43,916 (*Bayer Pharma AG v. Warner Chilcott Co., LLC et al.*, Case No. 13-cv-265). In the complaint, Bayer seeks unspecified monetary damages for the alleged infringement. On October 17, 2013, Bayer voluntarily dismissed its Complaint.

Although it is impossible to predict with certainty the outcome of any litigation, the Company believes that it has a number of strong defenses to the allegations in the complaints and intends to vigorously defend the litigations. These cases are in the early stages of litigation, and an estimate of the potential loss, or range of loss, if any, to the Company relating to these proceedings is not possible at this time.

*Drospirenone/Ethinyl Estradiol Tablets (Generic version of Yaz®)*. On November 5, 2007, Bayer Schering Pharma AG sued Watson and certain of its affiliates in the United States District Court for the District of Nevada, alleging that sales of Actavis drospirenone/ethinyl estradiol tablets, a generic version of Bayer's Yaz® tablets, would infringe numerous Bayer patents. *Bayer Schering Pharma AG v. Watson Pharmaceuticals, Inc., et al., Case No. 07cv1472*) The complaint sought damages and injunctive relief and included claims related to U.S. Patent No. 5,787,531, U.S. Patent No. RE 37,564, and U.S. Patent No. RE 37,838. Actavis filed an amended answer and counterclaims for a Declaratory Judgment of invalidity and/or non-infringement of U.S. Patent Nos. 5,798,338, 6,933,395, 6,958,326, 7,163,931 and RE 38,253. Thereafter, the U.S. Court of Appeals for the Federal Circuit ruled that U.S. Patent No. 5,787,531 was invalid and the claims related to that patent were dismissed. The District Court subsequently entered a consent judgment that Actavis does not infringe U.S. Patent Nos. 5,798,338, 6,933,395, 6,958,326, and 7,163,931, and dismissed with prejudice Bayer's claims related to U.S. Patent Nos. RE 37,838 and RE 38,253. The only patent still in dispute in the Nevada lawsuit is U.S. Patent No. RE 37,564 (the 564 Patent). On March 31, 2012, the court granted Bayer's motion for summary judgment that the 564 Patent is not invalid and denied Actavis' motion for summary judgment that the patent is invalid. Actavis timely filed a Notice of Appeal with the United States Court of Appeals for the Federal Circuit. On April 16, 2013, the U.S. Court of Appeals for the Federal Circuit reversed the District Court's decision, finding that the 564 patent is invalid. Actavis, which had suspended sales of the generic version of the product from January 7, 2012 through March 31, 2012, resumed selling the product in April 2013. On May 15, 2013, Bayer filed a petition for rehearing in the Federal Circuit. On August 12, 2013, the Federal Circuit denied Bayer's petition for rehearing and issued the mandate on August 20, 2013. If the Company is not ultimately successful in its defense of the lawsuit, it could adversely affect the Company's business, results of operations, financial condition and cash flows.

*Ibandronate Tablets (Generic version of Boniva®)*. On September 21, 2007, Hoffmann-La Roche Inc. sued Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. (both of which were subsequently acquired by Watson in 2009) in the United States District Court for the District of New Jersey, alleging that sales of Ibandronate Tablets, a generic version of Hoffmann-La Roche's Boniva® tablets, would infringe U.S. Patent Nos. 4,927,814 (the 814 Patent); 6,294,196 (the 196 Patent); and 7,192,938 (the 938 Patent) (*Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc., et al., Case No. 07cv4540*). The complaint sought damages and injunctive relief. Thereafter, Hoffmann-La Roche asserted additional claims, alleging infringement of U.S. Patent Nos. 7,410,957 (the 957 Patent) and 7,718,634 (the 634 patent) against Cobalt, and the parties entered into stipulations to dismiss Hoffmann-La Roche's claims related to the 196 and the 938 Patent. On August 24, 2010, the District Court granted Hoffmann-La Roche's motion for summary judgment that Cobalt would infringe at least one claim of the 814 patent. On March 17, 2012, the 814 patent expired, leaving the 957 and 634 patents as the only patents in suit. On May 7, 2012, the District Court granted the Company's motion for summary judgment that certain claims of the 634 patent are invalid. On October 1, 2012, the District Court granted Cobalt's motion for summary judgment that certain claims of the 957 patent are invalid. On January 25, 2013 the District Court denied Plaintiffs' motion for reconsideration of the summary judgment decisions finding the 634 patent and 957 patent claims invalid. The plaintiff has appealed. Oral argument on the appeal is scheduled for December 6, 2013. In June 2012, the Company began selling its generic version of Boniva®. The Company believes it has substantial meritorious defenses to the case. However, the Company has sold and is continuing to sell its generic version of Boniva®. Therefore, an adverse final appellate determination that one of the patents in suit is valid and infringed could have an adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Levonorgestrel/Ethinyl Estradiol Tablets (Generic version of Seasonique®)*. On March 6, 2008, Duramed (now known as Teva Women's Health) sued Watson in the United States District Court for the District of Nevada, alleging that

sales of Actavis levonorgestrel/ethinyl estradiol tablets, a generic version of Duramed's Seasonique® tablets, would infringe Duramed's U.S. Patent No. 7,320,969 (the '969 Patent') (*Duramed v. Watson Pharmaceuticals, Inc., et. al., Case No. 08cv00116*). The complaint sought damages and injunctive relief. On March 31, 2010, the District Court granted Duramed's motion for summary judgment that the asserted claims are not invalid as obvious. Actavis appealed and on March 25, 2011, the U.S. Court of Appeals for the Federal Circuit reversed the District Court and remanded the case for a determination of whether the asserted claims are obvious. On June 9, 2011, Duramed moved for a preliminary injunction to prevent Actavis from launching its product until after a trial on the merits. On June 16, 2011, the court denied Duramed's motion. Duramed appealed and also requested temporary injunctive relief during the pendency of its appeal (*Duramed v. Watson Laboratories, Case No. 3011-1438*). On July 27, 2011, the U.S. Court of Appeals for the Federal Circuit denied Duramed's request for temporary relief. Actavis launched its generic product on July 28, 2011. On November 10, 2011, the U.S. Court of Appeals for the Federal Circuit affirmed the District Court's denial of Duramed's preliminary injunction motion. On August 5, 2011, Duramed filed a motion in the District Court to amend its complaint to add a claim for damages as a result of the Company's launch of its generic product. On November 18, 2011, Actavis moved for summary judgment. On June 29, 2012, in a litigation involving the same patent, the United States District Court for the District of New Jersey held that the asserted claims of the

patent are invalid. On May 21, 2013 the United States Court of Appeals for the Federal Circuit affirmed the New Jersey District Court's judgment that the asserted claims of the patent are invalid. On July 9, 2012, Actavis filed a motion for judgment based on the collateral estoppel effect of the New Jersey decision. In response, on July 20, 2012, Duramed filed a motion to stay the litigation pending the Federal Circuit's decision in the appeal of the New Jersey decision. On July 25, 2012, the Court granted Duramed's motion to stay and denied without prejudice Actavis' motion for summary judgment and judgment based on collateral estoppels. On July 8, 2013, Duramed informed the Nevada District Court that it did not intend to pursue further appeals of the Federal Circuit's finding that the '969 Patent is invalid. On July 23, 2013 the case was dismissed with prejudice in favor of Actavis.

*Oxymorphone Extended-Release Tablets (Generic version of Opana® ER)*. On December 11, 2012, Endo Pharmaceuticals Inc. ( Endo ) sued Actavis and certain of its affiliates in the United States District Court for the Southern District of New York, alleging that sales of the Company's 7.5 mg and 15 mg oxymorphone extended-release tablets, generic versions of Endo's Opana® ER, infringe U.S. Patent Nos. 7,851,482; 8,309,122; and 8,329,216, which the USPTO recently issued or Endo recently acquired (*Endo Pharms. Inc. v. Actavis Inc. et al.*, Case No. 12-cv-8985). On July 11, 2013, the FDA approved Actavis' 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg oxymorphone extended-release tablets. On August 6, 2013, Endo filed a motion for a preliminary injunction seeking to prevent Actavis from selling its 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg oxymorphone extended-release tablets. On September 12, 2013, the Court denied Endo's motion for a preliminary injunction and Actavis began selling its generic versions of Opana® ER. On September 17, 2013, Endo filed a motion for an injunction pending appeal, which is currently pending. The Company believes it has substantial meritorious defenses to the case. However, Actavis has sold and is continuing to sell its generic versions of Opana® ER, 5mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg. Therefore, an adverse final determination that one of the patents in suit is valid and infringed could have an adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Tranexamic Acid Tablets (Generic version of Lysteda®)*. On July 7, 2011, Ferring B.V. sued Watson in the United States District Court for the District of Nevada, alleging that sales of the Company's tranexamic acid tablets, a generic version of Ferring's Lysteda® tablets, would infringe U.S. Patent No. 7,947,739 ( the '739 patent ) (*Ferring B.V. v. Watson Pharmaceuticals, Inc., et al.*, Case No. 3:11-cv-00481). On November 25, 2011, Ferring filed a second complaint in the District of Nevada alleging that sales of Actavis' tranexamic acid tablets would infringe U.S. Patent No. 8,022,106 ( the '106 patent ). (*Ferring B.V. v. Watson Pharmaceuticals, Inc., et al.*, Case No. 3:11-cv-00853). On November 9, 2012, Ferring filed a third complaint in the District of Nevada alleging that sales of Actavis' tranexamic acid tablets would infringe U.S. Patent No. 8,273,795 ( the '795 patent ) (*Ferring B.V. v. Watson Pharmaceuticals, Inc., et al.*, Case No. 2:12-cv-01935). The cases are still pending. The District Court has consolidated all three cases and has set a trial for January 21, 2014. On January 3, 2013, Actavis began selling its generic version of Lysteda®. On September 6, 2013, Ferring filed a fourth complaint in the District of Nevada alleging that sales of Actavis' tranexamic acid tablets would infringe U.S. Patent No. 8,487,055 ( the '795 patent ) (*Ferring B.V. v. Actavis, Inc., et al.*, Case No. 3:13-cv-00477). The fourth complaint also seeks damages for the alleged infringement of the '739, '106, '759, and '055 patents by Actavis' sales of its generic version of Lysteda®. The fourth case has not been consolidated with the first three cases. The Company believes it has substantial meritorious defenses to the case. However, Actavis has sold and is continuing to sell its generic version of Lysteda®. Therefore, an adverse final determination that one of the patents in suit is valid and infringed could have an adverse effect on the Company's business, results of operations, financial condition and cash flows.

### **Product Liability Litigation**

*Actonel Litigation*. Warner Chilcott is a defendant in approximately 272 cases and a potential defendant with respect to approximately 388 unfiled claims involving a total of approximately 668 plaintiffs and potential plaintiffs relating to the Warner Chilcott's bisphosphonate prescription drug ACTONEL. The claimants allege, among other things, that ACTONEL caused them to suffer osteonecrosis of the jaw ( ONJ ), a rare but serious condition that involves severe loss or destruction of the jawbone, and/or atypical fractures of the femur ( AFF ). All of the cases have been filed in either

federal or state courts in the United States. Warner Chilcott is in the initial stages of discovery in these litigations. The 388 unfiled claims involve potential plaintiffs that have agreed, pursuant to a tolling agreement, to postpone the filing of their claims against Warner Chilcott in exchange for Warner Chilcott's agreement to suspend the statutes of limitations relating to their potential claims. In addition, Warner Chilcott is aware of four purported product liability class actions that were brought against Warner Chilcott in provincial courts in Canada alleging, among other things, that ACTONEL caused the plaintiffs and the proposed class members who ingested ACTONEL to suffer atypical fractures or other side effects. It is expected that these plaintiffs will seek class certification. Of the approximately 672 total ACTONEL-related claims, approximately 155 include ONJ-related claims, approximately 498 include AFF-related claims and approximately 4 include both ONJ and AFF-related claims. Warner Chilcott is reviewing these lawsuits and potential claims and intends to defend these claims vigorously.

Sanofi-Aventis U.S. LLC ( Sanofi ), which co-promotes ACTONEL with Warner Chilcott on a global basis pursuant to a collaboration agreement, is a defendant in many of Warner Chilcott's ACTONEL product liability cases. In some of the cases, manufacturers of other bisphosphonate products are also named as defendants. Plaintiffs have typically asked for unspecified monetary and injunctive relief, as well as attorneys' fees. Under the collaboration agreement, Sanofi has agreed to indemnify Warner Chilcott, subject to certain limitations, for 50% of the losses from any product liability claims in Canada relating to ACTONEL and for 50% of the losses from any product liability claims in the United States and Puerto Rico relating to ACTONEL brought prior to April 1, 2010, which would include approximately 90 claims relating to ONJ and other alleged injuries that were pending as of March 31, 2010 and not subsequently dismissed. Pursuant to the April 2010 amendment to the collaboration agreement, Warner Chilcott will be fully responsible for any product liability claims in the United States and Puerto Rico relating to ACTONEL brought on or after April 1, 2010. Warner Chilcott may be liable for product liability, warranty or similar claims in relation to products acquired from The Procter & Gamble Company ( P&G ) in October 2009 in connection with Warner Chilcott's acquisition (the PGP Acquisition ) of P&G's global branded pharmaceutical's business ( PGP ), including ONJ-related claims that were pending as of the closing of the PGP Acquisition. Warner Chilcott's agreement with P&G provides that P&G will indemnify Warner Chilcott, subject to certain limits, for 50% of Warner Chilcott's losses from any such claims, including approximately 88 claims relating to ONJ and other alleged injuries, pending as of October 30, 2009 and not subsequently dismissed.

Warner Chilcott currently maintains product liability insurance coverage for claims aggregating between \$30 million and \$170 million, subject to certain terms, conditions and exclusions, and is otherwise responsible for any losses from such claims. The terms of Warner Chilcott's current and prior insurance programs vary from year to year and Warner Chilcott's insurance may not apply to, among other things, damages or defense costs related to the above mentioned HT or ACTONEL-related claims, including any claim arising out of HT or ACTONEL products with labeling that does not conform completely to FDA approved labeling.

In May 2013, Warner Chilcott entered into a settlement agreement in respect of up to 74 ONJ-related claims, subject to the acceptance thereof by the individual respective claimants. Warner Chilcott recorded a charge in the six months ended June 30, 2013 in the amount of \$2 million in accordance with ASC Topic 450 Contingencies in connection with Warner Chilcott's entry into the settlement agreement. This charge represents Warner Chilcott's current estimate of the aggregate amount that is probable to be paid by Warner Chilcott in connection with the settlement agreement. In September 2013, Warner Chilcott entered into a separate settlement agreement in respect of up to 53 additional ONJ-related claims, subject to the acceptance thereof by the individual respective claimants. Assuming that all of the relevant claimants accept the settlement agreements, approximately 545 ACTONEL-related claims would remain outstanding, of which approximately 28 include ONJ-related claims, approximately 498 include AFF-related claims and approximately 4 include both ONJ and AFF-related claims. However, it is impossible to predict with certainty (i) the number of such individual claimants that will accept the settlement agreement or (ii) the outcome of any litigation with claimants rejecting the settlement or other plaintiffs and potential plaintiffs with ONJ, AFF or other ACTONEL-related claims, and the Company can offer no assurance as to the likelihood of an unfavorable outcome in any of these matters. An estimate of the potential loss, or range of loss, if any, to the Company relating to proceedings with (i) claimants rejecting the settlement or (ii) other plaintiffs and potential plaintiffs with ONJ, AFF or other ACTONEL-related claims is not possible at this time. The Company believes it has substantial meritorious defenses to these cases and Warner Chilcott maintains product liability insurance against such cases. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. These actions, if successful, or if insurance does not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Alendronate Litigation.* Beginning in 2010, a number of product liability suits were filed against Watson and certain of its affiliates, as well as other manufacturers and distributors of alendronate, for personal injuries including femur fractures and ONJ allegedly arising out of the use of alendronate. Approximately 424 cases are pending against Watson and/or its affiliates in various state and federal courts, representing claims by approximately 547 plaintiffs.

These cases are generally at their preliminary stages. Watson believes that it will be defended in, and indemnified for, the majority of these claims by Merck & Co., the New Drug Application holder and manufacturer of the product sold by Watson during most of 2008. In addition, there are 139 lawsuits that name as a defendant Cobalt Laboratories, which Watson acquired in 2009 as part of its acquisition of the Arrow Group, in connection with Cobalt's manufacture and sale of alendronate. Nineteen of the cases naming Watson and/or Cobalt were consolidated for pre-trial proceedings as part of a multi-district litigation (MDL) matter pending in the United States District Court for the District of New Jersey (*In re: Fosamax (Alendronate Sodium) Products Liability Litigation, MDL No. 2243*). In 2012, the United States District Court for the District of New Jersey granted Watson's motion to dismiss all of the cases then pending against Watson and its affiliates in the New Jersey MDL matter. Several of the plaintiffs appealed the dismissal to the United States Court of Appeals for the Third Circuit and that appeal remains pending. Any cases filed against Watson or its affiliates in the District of New Jersey MDL after the Court's



January 2012 dismissal are subject to a case management order that calls for their dismissal unless plaintiffs can establish that their claims should be exempted from the 2012 dismissal order. To date, no plaintiff with a post-January 2012 complaint in the District of New Jersey against Watson or its affiliates has moved for such exemption have been or are expected to be dismissed. Several other cases are part of an MDL in the United States District Court for the Southern District of New York, where Watson has filed a similar motion to dismiss. The Court granted, in part, a motion to dismiss, which the Company expects will result in the Court removing several cases from its MDL docket. Seven additional cases are part of consolidated litigation in the California Superior Court (Orange County). The Orange County Court partially granted a similar motion to dismiss, but the Company has not yet been able to determine how that will affect the cases filed against and served on Watson and its affiliates. All cases pending in the state court of Missouri have been discontinued against Watson. Approximately 405 cases are pending as part of a mass tort coordinated proceeding in the Superior Court of New Jersey, Atlantic County. In that state court proceeding, responsive pleadings and discovery have been suspended with respect to Watson and its affiliates pending the court's decision on a motion to dismiss, which Watson filed in March 2012. The Court recently granted that motion, in part, but the Company has not yet assessed how that will affect the cases filed against Watson and its affiliates. The Company believes that it has substantial meritorious defenses to these cases and maintains product liability insurance against such cases. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. These actions, if successful, or if our indemnification arrangements or insurance do not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Fentanyl Transdermal System Litigation.* Beginning in 2009, a number of product liability suits were filed against Watson and other Company affiliates, as well as other manufacturers and distributors of fentanyl transdermal system products, for personal injuries or deaths allegedly arising out of the use of the fentanyl transdermal system products. Watson settled the majority of these cases in November 2012. There are approximately 9 cases that remain pending against Watson and/or its affiliates in state and federal courts that are not part of the November 2012 settlement, representing claims by approximately 21 plaintiffs. Discovery is ongoing. The Company believes it has substantial meritorious defenses to these cases and maintains product liability insurance against such cases. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. These actions, if successful, or if insurance does not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Hormone Replacement Therapy Litigation.* Beginning in early 2004, a number of product liability suits were filed against Watson, Warner Chilcott and certain other Company affiliates, as well as numerous other pharmaceutical companies, for personal injuries allegedly arising out of the use of hormone replacement therapy products, including but not limited to Watson products estropipate and estradiol and Warner Chilcott products FEMHRT, ESTRACE, ESTRACE Cream and medroxyprogesterone acetate. Under the purchase and sale agreement pursuant to which Warner Chilcott acquired FEMHRT from Pfizer Inc. (Pfizer) in 2003, Warner Chilcott agreed to assume certain product liability exposure with respect to claims made against Pfizer after March 5, 2003 and tendered to Warner Chilcott relating to FEMHRT products. Warner Chilcott successfully tendered 94 cases involving ESTRACE to Bristol-Myers Squibb Company (BMS) pursuant to an indemnification provision in the asset purchase agreement pursuant to which Warner Chilcott acquired this product. The purchase agreement included an indemnification agreement whereby BMS indemnified Warner Chilcott for product liability exposure associated with ESTRACE products shipped prior to July 2001.

Many of the cases originally filed against Watson, Warner Chilcott and/or other Company affiliates have been dismissed. Approximately 43 cases remain pending against Watson, Warner Chilcott and/or other Company affiliates in state and federal courts and that have not been tendered successfully to other parties. The remaining cases are pending in various courts including a consolidated action in the United States District Court for the Eastern District of Arkansas (*In re: Prempro Products Liability Litigation, MDL Docket No. 1507*) as well as proceedings in the federal district court for the District of Minnesota and in the Philadelphia Common Pleas Court. Discovery in the individual

cases has not been completed. The Company believes it has substantial meritorious defenses to these cases and maintains product liability insurance against such cases. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. These actions, if successful, or if insurance does not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Metoclopramide Litigation.* Beginning in 2009, a number of product liability suits were filed against certain Company affiliates, including legacy Actavis and Watson companies, as well as other manufacturers and distributors of metoclopramide, for personal injuries allegedly arising out of the use of metoclopramide. Approximately 1,260 cases are pending against Actavis, Watson and/or its affiliates in state and federal courts, representing claims by multiple plaintiffs. These cases are generally in their preliminary stages and discovery is ongoing. The Company believes that, with respect to the majority of the cases against the legacy Watson companies, it will be defended in and indemnified by Pliva, Inc., an affiliate of Teva, from whom the Company purchased its metoclopramide product line in late 2008. With respect to the cases pending against the legacy Actavis companies, the Company is actively defending them. The Company believes that it has substantial meritorious defenses to these cases and maintains product liability insurance

against such cases. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. These actions, if successful, or if our indemnification arrangements or insurance do not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Propoxyphene Litigation.* Beginning in 2011, a number of product liability suits were filed against Watson and certain of its affiliates, as well as other manufacturers and distributors of propoxyphene, for personal injuries including adverse cardiovascular events or deaths allegedly arising out of the use of propoxyphene. Cases are pending against Watson and/or its affiliates in various state and federal courts, representing claims by approximately 1,385 plaintiffs. Approximately 77 of the cases naming Watson were consolidated for pre-trial proceedings as part of a multi-district litigation (MDL) matter pending in the United States District Court for the Eastern District of Kentucky (*In re: Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, MDL No. 2226). Four of the MDL cases were voluntarily dismissed by plaintiffs with prejudice. On June 22, 2012, the court hearing the MDL cases granted the generic defendants' joint motion to dismiss the remaining MDL cases. Approximately 34 of the dismissed cases were appealed by the plaintiffs to the United States Court of Appeals for the Sixth Circuit and briefing is underway. No briefing schedule in these cases has been set. Approximately 35 of the cases naming Watson or its affiliates have been consolidated in a state court proceeding pending in the Superior Court of California in Los Angeles. These cases are at their preliminary stages and Watson intends to file demurrers and/or motions to dismiss. The Company believes that it has substantial meritorious defenses to these cases and maintains product liability insurance against such cases. However, litigation is inherently uncertain and the Company cannot predict the outcome of this litigation. These actions, if successful, or if insurance does not provide sufficient coverage against such claims, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

### **Qui Tam and Related Litigation**

*Governmental Investigation and False Claims Act Litigation.* Beginning in February 2012, Warner Chilcott, along with several of its current and former employees in its sales organization and certain third parties, received subpoenas from the United States Attorney for the District of Massachusetts. The subpoena received by Warner Chilcott seeks information and documentation relating to a wide range of matters, including sales and marketing activities, payments to people who are in a position to recommend drugs, medical education, consultancies, prior authorization processes, clinical trials, off-label use and employee training (including with respect to laws and regulations concerning off-label information and physician remuneration), in each case relating to all of Warner Chilcott's current key products. The Company is cooperating in responding to the subpoena but cannot predict or determine the impact of this inquiry on its future financial condition or results of operations.

The Company is aware of two *qui tam* complaints filed by former Warner Chilcott sales representatives and unsealed in February and March 2013 (*United States ex rel. Lisa A. Alexander and James P. Goan. v. Warner Chilcott PLC, et al.*, D. Mass. No. 11-10545 and *United States et al. ex rel. Chris Wible, v. Warner Chilcott PLC, et al.*, D. Mass. No. 11-11143). The unsealed *qui tam* complaints allege that Warner Chilcott violated Federal and state false claims acts through the promotion of all of Warner Chilcott's current key products by, among other things, making improper claims concerning the products, providing kickbacks to physicians and engaging in improper conduct concerning prior authorizations. The complaints seek, among other things, treble damages, civil penalties of up to eleven thousand dollars for each alleged false claim and attorneys' fees and costs. Other similar complaints may exist under seal. The United States of America has elected not to intervene at this time in each of the unsealed *qui tam* actions, stating at the times of the relevant seal expirations that its investigation of the allegations raised in the relevant complaint was continuing and, as such, it was not able to decide at such time whether to intervene in the action. The United States of America may later seek to intervene, and its election does not prevent the plaintiffs/relators from litigating the actions. Warner Chilcott intends to vigorously defend itself in the litigations. However, these cases are in the early stages of litigation, it is impossible to predict with certainty the outcome of any litigation, and the Company can offer no

assurance as to when the lawsuits will be decided, whether Warner Chilcott will be successful in its defense and whether any additional similar suits will be filed. If these claims are successful such claims could adversely affect the Company and could have a material adverse effect on the Company's business, financial condition, results of operation and cash flows.

*Governmental Reimbursement Investigations and Drug Pricing Litigation.* In November 1999, Schein Pharmaceutical, Inc., now known as Actavis Pharma, Inc. was informed by the U.S. Department of Justice that it, along with numerous other pharmaceutical companies, is a defendant in a *qui tam* action brought in 1995 under the U.S. False Claims Act currently pending in the U.S. District Court for the Southern District of Florida (the Florida Qui Tam Action). The Company has not been served in the *qui tam* action. A *qui tam* action is a civil lawsuit brought by an individual or a company (the *qui tam* relator) for an alleged violation of a federal statute, in which the U.S. Department of Justice has the right to intervene and take over the prosecution of the lawsuit at its option. Pursuant to applicable federal law, the *qui tam* action is under seal as to Actavis, Inc. The Company believes that the *qui tam* action

relates to whether allegedly improper price reporting by pharmaceutical manufacturers led to increased payments by Medicare and/or Medicaid. The Company believes that the Florida *Qui Tam* Action against the Company was dismissed without prejudice while still sealed as to the Company. Subsequently, the Company also received and responded to notices or subpoenas from the Attorneys General of various states, including Florida, Nevada, New York, California and Texas, relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid. On June 26, 2003, the Company received a request for records and information from the U.S. House Committee on Energy and Commerce in connection with that committee's investigation into pharmaceutical reimbursements and rebates under Medicaid. The Company produced documents in response to the request. Other state and federal inquiries regarding pricing and reimbursement issues are anticipated.

The Company and certain of its subsidiaries also are named as defendants in various lawsuits filed by numerous states and qui tam relators, including Wisconsin, Kentucky, Illinois, Mississippi, Missouri, South Carolina, Utah, Kansas and Louisiana captioned as follows: *State of Wisconsin v. Abbott Laboratories, et al.*, Case No. 04-cv-1709, Wisconsin Circuit Court for Dane County; *State of Wisconsin, ex rel., et al. v. Actavis Mid Atlantic LLC, et al.*, Case No. 11-cv-5544, Wisconsin Circuit Court for Dane County; *Commonwealth of Kentucky v. Alpharma, Inc., et al.*, Case Number 04-CI-1487, Kentucky Circuit Court for Franklin County; *State of Illinois v. Abbott Laboratories, Inc. et al.*, Civil Action No. 05-CH-02474, Illinois Circuit Court for Cook County; *State of Mississippi v. Abbott Laboratories, Inc. et al.*, Civil Action No. G2005-2021 S/2, Mississippi Chancery Court of Hinds County; *State of Missouri ex rel. Jeremiah W. (Jay) Nixon v. Mylan Laboratories, et al.*, Case No. 054-2486, Missouri Circuit Court of St. Louis; *State of South Carolina and Henry D. McMaster v. Watson Pharmaceuticals (New Jersey), Inc.*, In the Court of Common Pleas for the Fifth Judicial Circuit, State of South Carolina, County of Richland, C.A. No. 2006-CP-40-7152; *State of South Carolina and Henry D. McMaster v. Watson Pharmaceuticals (New Jersey), Inc.*, In the Court of Common Pleas for the Fifth Judicial Circuit, State of South Carolina, County of Richland, C.A. No. 2006-CP-40-7155; *State of Utah v. Actavis U.S., Inc., et al.*, In the Third Judicial District Court of Salt Lake County, Civil No. 07-0913719; *State of Kansas ex rel. Steve Six v. Watson Pharmaceuticals, Inc. and Watson Pharma, Inc.*, Case Number: 08CV2228, District Court of Wyandotte County, Kansas, Civil Court Department; and *State of Louisiana V. Abbott Laboratories, Inc., et al.*, Case No. 596144, Parish of East Baton Rouge, 19<sup>th</sup> Judicial District.

In 2011, Watson settled certain claims made against it by a relator in a *qui tam* action brought against the Company on behalf of the United States. The settlement of that *qui tam* action resolved all claims on behalf of the United States asserted in that action except for claims relating to the federal share of Medicaid payments made by the States of Alabama, Alaska, Kentucky, Idaho, Illinois, South Carolina and Wisconsin. The Company subsequently settled all claims, including the claims on behalf of the United States, brought by Alabama. In addition, the Company recently reached settlements in principle with the states of the Louisiana, South Carolina and Missouri, though the parties have yet to reach definitive agreements. The case against Watson on behalf of Kentucky was tried in November 2011. The jury reached a verdict in Watson's favor on each of Kentucky's claims against Watson. An agreed form of judgment has been entered and the case has been dismissed with prejudice. The case against Watson on behalf of Mississippi was tried from November 2012 through April 2013. On August 28, 2013, the court issued a ruling in favor of the state and awarded the state \$12.4 million in compensatory damages and civil penalties. A hearing is scheduled on the state's request for the imposition of punitive damages against Watson. The case against Watson on behalf of Kansas is scheduled for trial in January 2014.

With regard to the remaining drug pricing actions, the Company believes that it has meritorious defenses and intends to vigorously defend itself in those actions. The Company continually monitors the status of these actions and may settle or otherwise resolve some or all of these matters on terms that the Company deems to be in its best interests. However, the Company can give no assurance that it will be able to settle the remaining actions on terms it deems reasonable, or that such settlements or adverse judgments in the remaining actions, if entered, will not exceed the amounts of the liability reserves. Additional actions by other states, cities and/or counties are anticipated. These

actions and/or the actions described above, if successful, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

*Medicaid Drug Reimbursement Litigation.* In December 2009, the Company learned that numerous pharmaceutical companies, including certain subsidiaries of the Company, were named as defendants in a *qui tam* action pending in the United States District Court for the District of Massachusetts (*United States of America ex rel. Constance A. Conrad v. Abbott Laboratories, Inc. et. al., USDC Case No. 02-CV-11738-NG*). The seventh amended complaint, which was served on certain of the Company's subsidiaries in December 2009, alleges 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. In July 2011, the plaintiff served a tenth amended complaint that unseals the action in its entirety and continues to allege the previously asserted claims against certain subsidiaries of the Company. The Company's subsidiaries named in the action together with all other named defendants filed a Joint Motion to Dismiss the Tenth Amended Complaint on December 9, 2011. On February 25, 2013, the court granted the motion to dismiss as to all defendants. The plaintiff may appeal. On September 11, 2013, a new action was filed against certain Company subsidiaries as well as Warner Chilcott and numerous other pharmaceutical company defendants by the State of Louisiana based on the same core set of allegations as asserted in the Conrad *qui tam* action. Additional actions alleging similar claims could be asserted. The Company believes that it has meritorious defenses to the claims and intends to vigorously defend itself against such allegations. However, these actions or similar actions, if successful, could adversely affect the Company and could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

Actavis and its affiliates are involved in various other disputes, governmental and/or regulatory inspections, inquiries, investigations and proceedings that could result in litigation, and other litigation matters that arise from time to time. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect the Company, its results of operations, financial condition and cash flows.

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

### **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 speaks as of the date of this Quarterly 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 plc**

*We may not realize all of the anticipated benefits of the transaction with Warner Chilcott or those benefits may take longer to realize than expected. We may also encounter significant unexpected difficulties in integrating the two businesses.*

Our ability to realize the anticipated benefits of the transaction with Warner Chilcott will depend, to a large extent, on our ability to integrate the Actavis, Inc. and the Warner Chilcott businesses. The combination of two independent businesses is a complex, costly and time-consuming process. As a result, we will be required to devote significant management attention and resources to integrating the business practices and operations of Actavis, Inc. and Warner Chilcott. The integration process may disrupt the businesses and, if implemented ineffectively, would preclude realization of the full benefits expected by us. Our failure to meet the challenges involved in integrating the two businesses to realize the anticipated benefits of the transaction could cause an interruption of, or a loss of momentum in, our activities and could adversely affect our results of operations.

In addition, the overall integration of the businesses may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management's attention. The difficulties of combining the operations of the companies include, among others:

the diversion of management's attention to integration matters;

difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from combining the business of Actavis, Inc. with that of Warner Chilcott;

difficulties in the integration of operations and systems;

difficulties in the assimilation of employees;

difficulties in managing the expanded operations of a significantly larger and more complex company;

challenges in keeping existing customers and obtaining new customers; and

challenges in attracting and retaining key personnel.

Many of these factors will be outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact our business, financial condition and results of operations. In addition, even if the operations of the businesses of Actavis, Inc. and Warner Chilcott are integrated successfully, we may not realize the full benefits of the transaction, including the synergies, cost savings or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all. Or, additional unanticipated costs may be incurred in the integration of the businesses of Actavis, Inc. and Warner Chilcott. All of these factors could cause a reduction to our earnings per share, decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our ordinary shares. As a result, we cannot assure you that the combination of the Actavis, Inc. and Warner Chilcott businesses will result in the realization of the full benefits anticipated from the transaction.



*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 U.S. Food and Drug Administration (the FDA) and other regulatory authorities;

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

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;

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;

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 research and development ( 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, product promotional activities, drug pricing or reimbursement, product liability, customers or other issues;

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

our ability to successfully integrate newly acquired businesses; and

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

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.***

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 newly acquired businesses into our business operations, our business could be adversely affected.***

We will need to successfully integrate the operations of newly acquired businesses, including Warner Chilcott, with our business operations. Integrating the operations of new businesses with that of our own will be a complex and time-consuming process. Prior to each acquisition, the acquired business 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 other businesses 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.

These risks may be accentuated if the majority of the former businesses' operations, employees and customers are located outside of the United States, such as with the acquisition of the legacy Actavis Group. 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.

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

***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 anti-kickback 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 plc, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. We are committed to conducting the sales and marketing of our 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 of our subsidiaries, 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.

Some of the statutes and regulations that govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. Certain other requirements, such as those under the PPACA's Sunshine Act provisions, are new and their breadth and application are uncertain. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the U.S. Department of Justice and other agencies have increased their enforcement activities with respect to the sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. Beginning in February 2012, Warner Chilcott, along with several current and former employees in its sales organization and certain third parties, received subpoenas from the United States Attorney for the District of Massachusetts. The subpoena Warner Chilcott received sought information and documentation

relating to a wide range of matters, including sales and marketing activities, payments to people who are in a position to recommend drugs, medical education, consultancies, prior authorization processes, clinical trials, off-label use and employee training (including with respect to laws and regulations concerning off-label information and physician remuneration), in each case relating to all of our current key products. We cannot predict or determine the impact of this inquiry on our future financial condition or results of operations.

A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacture and/or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. The U.S. Attorney's investigation and any other threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could be used productively on other aspects of our business. Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows.

***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 active pharmaceutical ingredient ( 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 the FDA or other regulatory agencies;

changing review and approval policies and standards at the 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 R&D 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 the 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.

***If generic products that compete with any of our branded pharmaceutical products are approved and sold, sales of our products will be adversely affected.***

As a result of our acquisition of Warner Chilcott, specialty branded products now comprise a large percentage of our total revenues. Generic equivalents for branded pharmaceutical products are typically sold at a lower cost than the branded product. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. In addition, legislation enacted in most U.S. states and Canadian provinces allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded



product, in the absence of specific instructions from the prescribing physician. As a result, branded products typically experience a significant loss in revenues following the introduction of a competing generic product. Our branded pharmaceutical products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of the branded pharmaceutical products we sell, because our patent protection expires or because our patent protection is not sufficiently broad or enforceable. In addition, we may not be successful in our efforts to extend the proprietary protection afforded our branded products through the development and commercialization of proprietary product improvements and new and enhanced dosage forms.

Our ACTONEL products no longer have patent protection in Canada or the Western European countries in which we sell these products, and ASACOL is not protected by a patent in the United Kingdom. In addition, other products such as ESTRACE Cream and FEMHRT are not protected by patents in the United States where we sell these products. Generic equivalents are currently available in Canada and Western Europe for ACTONEL and in the United States for our DORYX products, certain versions of our FEMHRT products, FEMCON FE and certain other less significant products.

During the next few years, additional products of ours will lose patent protection or likely become subject to generic competition. For example, our ASACOL 400 mg product and our DELZICOL product lost U.S. patent protection in July 2013; our ACTONEL once-a-week product will lose U.S. patent protection in June 2014 (including a 6-month pediatric extension of regulatory exclusivity); generic versions of our LOESTRIN 24 FE product may enter the market as early as January 2014 pursuant to settlement agreements previously entered into; and generic versions of our ENABLEX product may enter the market as early as March 2016 pursuant to settlement agreements previously entered into. Some of our products may also become subject to generic competition prior to the expiration of patent protection in the event a generic competitor elects to launch its generic equivalent product at-risk. Competition from generic equivalents could result in a material impairment of our intangible assets or the acceleration of amortization on our non-impaired intangible assets and have a material adverse impact on our revenues, financial condition, results of operations and cash flows.

***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, and particularly following the Warner Chilcott acquisition, we anticipate continuing our product development expenditures for our Actavis Specialty Brands business segment, including Warner Chilcott. In order to grow and achieve success in our business, we must continually identify, develop, acquire and license new products that we can ultimately market. There are many difficulties and uncertainties inherent in pharmaceutical research and development, and there is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including late in the process after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals and payer reimbursement, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. For example in 2013, we initiated a Phase 3 clinical trial for our Esmya™ product for treatment of uterine fibroids. We also have new hormonal contraceptive therapy products in various stages of development from preclinical development to Phase 3 development, as well as osteoporosis products in preclinical and clinical development and dermatology and infectious disease products in various stages of clinical development, among others. 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 or products recently acquired in the Warner Chilcott acquisition, among others, 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.

***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 Inc. ( 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, only draft guidance has been issued by the FDA. Even if the FDA enacts rules and regulations concerning the development and approval of biosimilars, such regulations could include provisions that provide up to twelve or more years of data exclusivity for the original developer of the product on which a 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 will likely 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.

***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. 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, 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. During the next five years, additional products acquired pursuant to the Warner Chilcott acquisition will lose patent protection or likely become subject to generic competition. For example, our newly acquired ASACOL 400 mg product and our DELZICOL product lost U.S. patent protection in July 2013, our ACTONEL once-a-week product will lose U.S. patent protection in June 2014 (including a 6-month pediatric extension of regulatory exclusivity), generic versions of our LOESTRIN 24 FE product may enter the market as early as January 2014 pursuant to settlement agreements previously entered into; and generic versions of our ENABLEX product may enter the market as early as March 2016 pursuant to settlement agreements previously entered into. Some of our products may also become subject to generic competition prior to the expiration of patent protection in the event a generic competitor elects to launch its generic equivalent product at-risk. For example, although our DORYX patent does not expire until 2022, and Warner Chilcott and Mayne filed infringement lawsuits against Mylan and Impax arising from their ANDA filings with respect to our DORYX 75 mg and 100 mg products, generic versions of such products were launched at-risk in January 2011 following the FDA's approval of their respective ANDAs.

Generic competitors to our brand products may also challenge the validity or enforceability of the patents protecting our products or otherwise seek to circumvent them. For example, Warner Chilcott has received a challenge relating to its ASACOL HD products. In September 2011, Warner Chilcott received a Paragraph IV certification notice letter from Zydus Pharmaceuticals (USA) Inc. ( Zydus ) indicating that Zydus had submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of ASACOL HD prior to the expiration of U.S Patent No. 6,893,662. Warner Chilcott filed suit against Zydus in November 2011, and that case is currently pending. Trial is scheduled to begin on December 9, 2013.

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;

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.

Further, in August 2012, Bayer Pharma AG (together with its affiliates, Bayer) filed a complaint against Warner Chilcott alleging that its manufacture, use, offer for sale, and/or sale of LO LOESTRIN FE infringes Bayer's U.S. Patent No. 5,980,940. In the complaint, Bayer seeks injunctive relief and unspecified monetary damages for the alleged infringement. In December 2012, Bayer amended the complaint to add a claim seeking to invalidate the Company's 984 Patent, which covers the LO LOESTRIN FE 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.

***Our Anda 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 Anda 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 Anda 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 Warner Chilcott products and collectively accounted for approximately 30% and 65% of Actavis, Inc. 's and Warner Chilcott 's annual net revenues in 2012, respectively. 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.



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***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 Actavis, Inc.'s revenues, such as INFe®, metoprolol succinate extended release tablets, methylphenidate hydrochloride extended release tablets, and a significant number of our oral contraceptive and controlled substance products. We expect to continue to rely on our third-party manufacturing partners, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc. for methylphenidate ER, Mayne for DORYX, Contract Pharmaceuticals Limited Canada (CPL) for ESTRACE Cream and NPI for ACTONEL and ATELVIA. GlaxoSmithKline plc (GSK) currently manufactures our ASACOL 400 mg product sold in the United Kingdom. CPL, which manufactures our ESTRACE Cream product, recently closed its manufacturing facility in Buffalo, New York and transferred its operations at that location to its facilities in Mississauga, Canada. Such transfers are subject to regulatory approvals, and the failure to obtain such approvals in a timely manner may delay production at the new facility and result in an interruption in our product supply. 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 average wholesale price ( 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 operations, financial condition and cash flows.

***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.

***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. 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 Anda 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 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 shareholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing shareholders. 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 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 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, particularly following the legacy Actavis Group and Warner Chilcott acquisitions, 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 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;

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

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

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

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;

difficulties and costs of staffing and managing foreign operations, including cultural and language differences and additional employment regulations, union workforce negotiations and potential disputes in the new jurisdictions in which we operate;

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, if enacted, could have a significant adverse impact on our effective tax rate.

***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.



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***Prior to the legacy Actavis Group acquisition, the legacy 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 legacy 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.

***We have incurred and will continue to incur significant transaction, integration and restructuring costs in connection with recent transactions, including the legacy Actavis Group and Warner Chilcott acquisitions.***

We have incurred significant transaction costs related to the legacy Actavis Group acquisition. We have incurred and will continue to incur significant transaction costs related to the Warner Chilcott acquisition. In addition, we will incur integration costs and restructuring costs as we integrate the legacy Actavis, Inc. and Warner Chilcott businesses. Although we expect that the realization of benefits and efficiencies related to the integration of the businesses may offset these transaction costs, integration costs and restructuring costs over time, no assurances can be made that this net benefit will be achieved in the near term, or at all. The failure to realize the expected benefits and efficiencies related to the integration of the businesses 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 legacy Actavis Group or Warner Chilcott acquisitions would negatively affect the combined company's financial results.***

Upon consummation of the legacy Actavis Group acquisition, we recorded goodwill of approximately \$2,868.8 million. We will also record goodwill following the Warner Chilcott acquisition. 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 legacy Actavis Group or Warner Chilcott acquisitions would negatively affect our results of operations. We also allocated approximately \$2,268.0 million of the total consideration paid in connection with the legacy Actavis Group acquisition to identified intangibles representing currently marketed products ( CMP ) and approximately \$272.9 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 are 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.

### **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 plc, 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 the 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 plc or our subsidiaries will be granted or that the FDA will not seek to impose additional sanctions against Actavis plc 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 and regulations could result in DEA suspending, terminating or refusing to renew And a 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 the FDA, the Department of Justice, the U.S. Attorney 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. 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.

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***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 Medicare Prescription Drug and Modernization Act of 2003 ( 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 the 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, on April 5, 2013, two putative class actions were filed against Actavis, Inc. and certain affiliates alleging that Watson Pharmaceuticals, Inc.'s 2009 patent lawsuit settlement with Warner Chilcott related to Loestrin 24 Fe<sup>®</sup> (norethindrone acetate/ethinyl estradiol tablets and ferrous fumarate tablets,

Loestrin 24 ) is unlawful. The complaints, both asserted on behalf of putative classes of end-payors, generally allege that Watson and another generic manufacturer improperly delayed launching generic versions of Loestrin 24<sup>®</sup> in exchange for substantial payments from Warner Chilcott, which at the time was an unrelated company, in violation of federal and state antitrust and consumer protection laws. Further, 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<sup>®</sup> 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.

***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.

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 our 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. We maintain 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 all of our 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.

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, Actavis Pharma and Warner Chilcott 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 did not offer a full line of brand products to our customers prior to our acquisition of Warner Chilcott, we have been 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 the Company.



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 legacy Actavis Group and Warner Chilcott acquisitions, 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 legacy Actavis Group acquisition.

#### **Additional Risks Related to the Warner Chilcott Acquisition and Re-domiciliation of Actavis to Ireland**

***We incurred direct and indirect costs as a result of the transaction with Warner Chilcott.***

We incurred costs and expenses in connection with and as a result of the transaction with Warner Chilcott. These costs and expenses included professional fees to comply with Irish corporate and tax laws and financial reporting requirements, costs and expenses incurred in connection with holding a majority of the meetings of the our board of directors and certain executive management meetings in Ireland, as well as any additional costs we may incur going forward as a result of our new corporate structure. These costs may exceed the costs historically borne by Actavis, Inc. and Warner Chilcott.

***The Internal Revenue Service (the IRS ) may not agree with our conclusion to treat Actavis plc as a foreign corporation for U.S. federal tax purposes following the transaction with Warner Chilcott.***

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to section 7874 of the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes.

For us to be treated as a foreign corporation for U.S. federal tax purposes under section 7874, either (i) the former stockholders of Actavis, Inc. must own (within the meaning of section 7874) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Actavis, Inc., which is referred to in this report as the ownership test , or (ii) we must have substantial business activities in Ireland (taking into account the activities of our expanded affiliated group). Immediately following the transaction with Warner Chilcott, the former Actavis, Inc. stockholders owned less than 80% (by both vote and value) of our shares after the transaction by reason of their ownership of shares of Actavis, Inc. stock. As a result, under current law, we are treated as a foreign corporation for U.S. federal tax purposes. We cannot assure you that the IRS will agree with the position that the ownership test is satisfied, however. There is limited guidance regarding the section 7874 provisions, including the application of the ownership test.

***Section 7874 likely will limit Actavis, Inc. s and its U.S. affiliates ability to utilize their U.S. tax attributes to offset certain U.S. taxable income, if any, generated by the transaction with Warner Chilcott or certain specified transactions for a period of time following the transaction.***

Following the acquisition of a U.S. corporation by a foreign corporation, section 7874 can limit the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, we currently expect that following the transaction, this limitation will apply and as a result, Actavis, Inc. currently does not expect that it or its U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain specified taxable transactions.

- 45 -

***Future changes to the international tax laws could adversely affect us.***

Under current law, we expect to be treated as a foreign corporation for U.S. federal tax purposes. However, changes to the inversion rules in section 7874 or the U.S. Treasury Regulations promulgated thereunder could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such changes could have prospective or retroactive application to us, Actavis, Inc., our respective stockholders, shareholders and affiliates, and/or the transaction with Warner Chilcott. In addition, recent legislative proposals have aimed to expand the scope of U.S. corporate tax residence, and such legislation, if passed, could have an adverse effect on us.

Moreover, the U.S. Congress, the Organisation for Economic Co-operation and Development and other Government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of base erosion and profit shifting, where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

***We will seek Irish High Court approval of the creation of distributable reserves. We expect this will be forthcoming but cannot guarantee this.***

Under Irish law, dividends may only be paid and share repurchases and redemptions must generally be funded only out of distributable reserves, which we do not have immediately following the closing of our acquisition of Warner Chilcott. The creation of distributable reserves requires the approval of the Irish High Court and, in connection with seeking such court approval, the approval of the former Actavis, Inc. stockholders and Warner Chilcott shareholders has been obtained. The approval of the Irish High Court is expected within 15 weeks following the closing on October 1, 2013. We are not aware of any reason why the Irish High Court would not approve the creation of distributable reserves; however, the issuance of the required order is a matter for the discretion of the Irish High Court. In the event that distributable reserves are not created, no distributions by way of dividends, share repurchases or otherwise will be permitted under Irish law until such time as the group has created sufficient distributable reserves from its trading activities.

***As a result of different shareholder voting requirements in Ireland relative to laws in effect in certain states in the United States, we may have less flexibility with respect to certain aspects of capital management than companies organized in the United States.***

Under Irish law, our authorized share capital can be increased by an ordinary resolution of our shareholders and the directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our articles of association or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders to subscribe for new issuances of shares for cash, but allows shareholders to authorize the waiver of the statutory preemption rights by way of special resolution with respect to any particular allotment of shares. Accordingly, our articles of association contain, as permitted by Irish company law, a provision authorizing the board to issue new shares for cash without offering preemption rights. The authorization of the directors to issue shares and the authorization of the waiver of the statutory preemption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our securities.

***We are incorporated in Ireland, and Irish law differs from the laws in effect in the United States and may afford less protection to, or otherwise adversely affect, our shareholders.***

Our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction of the United States. As an Irish company, we are governed by the Irish Companies Acts (the Companies Act ). The Companies Act differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, mergers, amalgamations and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. For example, under Irish law, the duties of directors and officers of a company are generally owed to the company only. As a result, shareholders of Irish companies do not have the right to bring an action against the directors or officers of a company, except in limited circumstances. In addition, depending on the circumstances, you may be subject to different or additional tax consequences under Irish law as a result of your acquisition, ownership and/or disposition of our ordinary shares, including, but not limited to, Irish stamp duty, dividend withholding tax and capital acquisitions tax.

***We are an Irish company and it may be difficult for you to enforce judgments against us or certain of our officers and directors.***

We are incorporated in Ireland and a substantial portion of our assets are located in jurisdictions outside the United States. In addition, some of our officers and directors reside outside the United States, and some or all of their respective assets are or may be located in jurisdictions outside of the United States. Therefore, it may be difficult for investors to effect service of process against us or such officers or directors or to enforce against us or them judgments of U.S. courts predicated upon civil liability provisions of the U.S. federal securities laws.

There is no treaty between Ireland and the United States providing for the reciprocal enforcement of foreign judgments. The following requirements must be met before the foreign judgment will be deemed to be enforceable in Ireland:

the judgment must be for a definite sum;

the judgment must be final and conclusive; and

the judgment must be provided by a court of competent jurisdiction.

An Irish court will also exercise its right to refuse judgment if the foreign judgment was obtained by fraud, if the judgment violated Irish public policy, if the judgment is in breach of natural justice or if it is irreconcilable with an earlier judgment. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere. Judgments of U.S. courts of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts if deemed to be contrary to public policy in Ireland.

***A transfer of Company Ordinary Shares, other than by means of the transfer of book-entry interests in the Depository Trust Company ( DTC ), may be subject to Irish stamp duty.***

Transfers of Company Ordinary Shares effected by means of the transfer of book entry interests in DTC will not be subject to Irish stamp duty. However, if you hold your Company Ordinary Shares directly rather than beneficially through DTC, any transfer of your Company Ordinary Shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty could adversely affect the price of your shares.

***In certain limited circumstances, dividends we pay may be subject to Irish dividend withholding tax.***

While we do not currently contemplate paying dividends upon our ordinary shares, in certain limited circumstances, dividend withholding tax (currently at a rate of 20%) may arise in respect of dividends, if any, paid on our ordinary shares. A number of exemptions from dividend withholding tax exist such that shareholders resident in the U.S. and shareholders resident in certain countries may be entitled to exemptions from dividend withholding tax.

Shareholders resident in the U.S. that hold their shares through DTC will not be subject to dividend withholding tax provided the addresses of the beneficial owners of such shares in the records of the brokers holding such shares are recorded as being in the U.S. (and such brokers have further transmitted the relevant information to a qualifying intermediary appointed by us. Similarly, shareholders resident in the U.S. that hold their shares outside of DTC will not be subject to dividend withholding tax if, in the case of former Actavis, Inc. shareholders, they provide a

completed IRS Form 6166 to our transfer agent to confirm their U.S. residence and claim an exemption, or, in the case of former Warner Chilcott shareholders, such shareholders previously filed valid dividend withholding tax forms with Warner Chilcott or its transfer agent in respect of their Warner Chilcott shareholdings. All new U.S. resident shareholders in Actavis plc that hold their shares outside of DTC and shareholders resident in certain other countries (irrespective of whether they hold their shares through DTC or outside DTC) will not be subject to dividend withholding tax provided the beneficial owners of such shares have furnished completed and valid dividend withholding tax forms or an IRS Form 6166, as appropriate, to our transfer agent or their brokers (and such brokers have further transmitted the relevant information to our transfer agent). However, other shareholders may be subject to dividend withholding tax, which could adversely affect the price of your shares.

***Dividends received by Irish residents and certain other shareholders may be subject to Irish income tax.***

Shareholders entitled to an exemption from Irish dividend withholding tax on dividends received from us will not be subject to Irish income tax in respect of those dividends, unless they have some connection with Ireland other than their shareholding in us (for example, they are resident in Ireland). Shareholders who are not resident nor ordinarily resident in Ireland but who are not entitled to an exemption from Irish dividend withholding tax will generally have no further liability to Irish income tax on those dividends which suffer dividend withholding tax.

***Company Ordinary Shares received by means of a gift or inheritance could be subject to Irish capital acquisitions tax.***

Irish capital acquisitions tax ( CAT ) could apply to a gift or inheritance of Company Ordinary Shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because Company Ordinary Shares are regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT. Gifts and inheritances passing between spouses are exempt from CAT. Children have a tax-free threshold of 225,000 in respect of taxable gifts or inheritances received from their parents.

**ITEM 6. EXHIBITS.**

Exhibits See Exhibit Index attached.

**SIGNATURES**

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

ACTAVIS PLC  
Registrant

By: /s/ R. Todd Joyce  
R. Todd Joyce  
Chief Financial Officer Global  
(Principal Financial Officer)

By: /s/ James C. D Arecca  
James C. D Arecca  
Chief Accounting Officer  
(Principal Accounting Officer)

Date: October 31, 2013



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**ACTAVIS PLC**

**EXHIBIT INDEX TO FORM 10-Q**

**For the Quarterly Period Ended September 30, 2013**

**Exhibit Index**

- 2.1 Transaction Agreement, dated May 19, 2013, by and among Actavis, Inc., Warner Chilcott Public Limited Company, Actavis Limited (now known as Actavis plc), Actavis Ireland Holding Limited, Actavis W.C. Holding LLC (now known as Actavis W.C. Holding Inc.) and Actavis W.C. Holding 2 LLC (now known as Actavis W.C. Holding 2 Inc.) (incorporated by reference to Exhibit 2.1 of Actavis, Inc.'s Current Report on Form 8-K filed with the SEC on May 23, 2013).
- 3.1 Certificate of Incorporation of Actavis plc (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 2, 2013).
- 3.2 Amended and Restated Memorandum and Articles of Association of Actavis plc (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed with the SEC on October 2, 2013).
- 4.1 Fourth Supplemental Indenture, dated as of October 1, 2013, by and among Actavis, Inc., Actavis plc and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 2, 2013).
- 4.2 Third Supplemental Indenture, dated as of October 1, 2013, by and among Warner Chilcott Company, LLC, Warner Chilcott Finance LLC, Actavis plc and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, filed with the SEC on October 2, 2013).
- 10.1 Term Loan Amendment Agreement, by and among Actavis, Inc., Bank of America, N.A., as Administrative Agent, and the lenders party thereto, dated as of August 1, 2013 (incorporated by reference to Exhibit 10.1 of Actavis, Inc.'s Current Report on Form 8-K, filed with the SEC on August 2, 2013).
- 10.2 Revolver Loan Amendment Agreement, by and among Actavis, Inc., Bank of America, N.A., as Administrative Agent, and the lenders party thereto, dated as of August 1, 2013 (incorporated by reference to Exhibit 10.2 of Actavis, Inc.'s Current Report on Form 8-K, filed with the SEC on August 2, 2013).
- 10.3 Amended and Restated Actavis Term Loan Credit Facility, by and among Actavis WC Holding S.à r.l., Actavis, Inc., Actavis plc, the lenders from time to time party thereto and Bank of America, N.A., as Administrative Agent, dated as of October 1, 2013 (incorporated by reference to Exhibit 10.3 of Actavis, Inc.'s Current Report on Form 8-K, filed with the SEC on August 2, 2013).
- 10.4 Amended and Restated Actavis Revolving Credit Facility, by and among Actavis WC Holding S.à r.l., Actavis, Inc., Actavis plc, the lenders from time to time party thereto and Bank of America, N.A., as Administrative Agent, dated as of October 1, 2013 (incorporated by reference to Exhibit 10.4 of Actavis, Inc.'s Current Report on Form 8-K, filed with the SEC on August 2, 2013).
- 10.5 WC Term Loan Credit and Guaranty Facility, dated as of August 1, 2013, by and among Actavis plc (formerly Actavis Limited), Warner Chilcott Corporation, WC Luxco S.à r.l, Warner Chilcott Company, LLC, Warner Chilcott Finance LLC, the lenders from time to time party thereto and Bank of America, N.A., as administrative agent thereunder (incorporated by reference to Exhibit 10.5 to Actavis, Inc.'s Current Report on Form 8-K, filed with the SEC on August 2, 2013).



10.6	Form of Deed of Indemnification, Actavis plc (incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K, filed with the SEC on October 2, 2013)
10.7	Form of Indemnification Agreement, Actavis W.C. Holding Inc. (incorporated by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K, filed with the SEC on October 2, 2013)
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14a of the Securities Exchange Act of 1934.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14a of the Securities Exchange Act of 1934.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. of Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. of Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Label Definition Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Furnished herewith and not filed for purposes of Section 18 of the Exchange Act.

\*\*\* In accordance with Rule 406T of Regulation S-T, this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.