

# WARNER CHILCOTT PLC

## FORM 8-K

(Current report filing)

Filed 08/25/10 for the Period Ending 08/24/10

Telephone	353 41 685 6983
CIK	0001323854
Symbol	WCRX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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

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**Form 8-K**

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**Current Report**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of Report: August 25, 2010  
Date of earliest event reported: August 24, 2010**

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**Warner Chilcott Public Limited Company**  
(Exact name of registrant as specified in its charter)

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**Ireland**  
(State or other jurisdiction  
of incorporation)

**0-53772**  
(Commission  
File Number)

**98-0626948**  
(IRS Employer  
Identification No.)

**Unit 19 Ardee Business Park  
Hale Street  
Ardee, Co. Louth, Ireland**  
(Address of principal executive offices, including zip code)

**+353 41 685 6983**  
(Registrant's telephone number, including area code)

**Not Applicable**  
(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other Events**

On August 24, 2010, Warner Chilcott Public Limited Company (the “Company”) issued a press release announcing that it had received the Food and Drug Administration’s response to a citizen petition the Company had filed regarding its ASACOL 400 mg and ASACOL HD products. A copy of the Company’s press release is filed as Exhibit 99.1 hereto and is incorporated by reference into this Item 8.01.

**Item 9.01 Financial Statements and Exhibits**

(d) *Exhibits* .

99.1 Press Release issued August 24, 2010

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

W ARNER C HILCOTT P UBLIC L IMITED C OMPANY

By:  /s/ P AUL H ERENDEEN

Name: Paul Herendeen

Title: Executive Vice President and Chief Financial Officer

Date: August 25, 2010

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued August 24, 2010

**NEWS RELEASE****Warner Chilcott Announces Receipt of FDA Response to Citizen Petition**

ARDEE, Ireland, August 24, 2010 – Warner Chilcott plc (NASDAQ: WCRX) today announced that it has received the Food and Drug Administration’s (“FDA’s”) response to a citizen petition it had filed regarding its ASACOL and ASACOL HD products. In its petition, Warner Chilcott requested that the FDA (1) issue bioequivalence guidance for mesalamine delayed-release tablets, (2) not approve any abbreviated new drug applications (“ANDAs”) referencing ASACOL and/or ASACOL HD unless the proposed generic product is shown to be bioequivalent based on appropriate data from a clinical efficacy endpoint study, comparative pharmacokinetic testing and rigorous in vitro dissolution testing and (3) deny any waiver of bioequivalence testing for either ASACOL or ASACOL HD based on a showing of bioequivalence in the other strength. In its joint-response to the citizen petitions of the Company and another petitioner, the FDA has granted in part and denied in part various aspects of the citizen petitions. The impact of the FDA’s response will depend upon the particular facts of any ANDA filed referencing ASACOL and/or ASACOL HD.

A copy of the FDA’s response letter is available in the Investor Relations section of the Company’s website at [www.wcrx.com](http://www.wcrx.com). In addition, the Company’s citizen petition and related information and the FDA’s response letter are, or will be made available, on the [www.regulations.gov](http://www.regulations.gov) website.

**About Warner Chilcott**

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the gastroenterology, women’s healthcare, dermatology and urology segments of the North American and Western European pharmaceuticals markets. The Company is fully integrated with internal resources dedicated to the development, manufacturing and promotion of its products. WCRX-G.

**Forward Looking Statements**

This press release contains forward-looking statements, including statements concerning our operations, our anticipated financial performance and financial condition, and our business plans and growth strategy and product development efforts. These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words “may,” “might,” “will,” “should,” “estimate,” “project,” “plan,” “anticipate,” “expect,” “intend,” “outlook,” “believe”

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and other similar expressions are intended to identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates. These forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain and subject to a number of risks and uncertainties. The following represent some, but not necessarily all, of the factors that could cause actual results to differ from historical results or those anticipated or predicted by our forward-looking statements: our substantial indebtedness; competitive factors in the industry in which we operate (including the approval and introduction of generic or branded products that compete with our products); our ability to protect our intellectual property; a delay in qualifying our manufacturing facilities that produce our products or production or regulatory problems with either third party manufacturers or API suppliers upon whom we may rely for some of our products or our own manufacturing facilities; pricing pressures from reimbursement policies of private managed care organizations and other third party payors, government sponsored health systems, the continued consolidation of the distribution network through which we sell our products, including wholesale drug distributors and the growth of large retail drug store chains; the loss of key senior management or scientific staff; adverse outcomes in our outstanding litigation or an increase in the number of litigation matters to which we are subject; government regulation, including domestic and foreign health care reform, affecting the development, manufacture, marketing and sale of pharmaceutical products, including our ability and the ability of companies with whom we do business to obtain necessary regulatory approvals; our ability to manage the growth of our business by successfully identifying, developing, acquiring or licensing new products at favorable prices and marketing such new products; our ability to obtain regulatory approval and customer acceptance of new products, and continued customer acceptance of our existing products; changes in tax laws or interpretations that could increase our consolidated tax liabilities; our ability to realize the anticipated opportunities from our acquisition of the global branded pharmaceuticals business from The Procter and Gamble Company; the other risks identified in our periodic filings including our Annual Report on Form 10-K for the year ended December 31, 2009, and from time-to-time in our other investor communications.

We caution you that the foregoing list of important factors is not exclusive. In addition, in light of these risks and uncertainties, the matters referred to in our forward-looking statements may not occur. We undertake no obligation to publicly update or revise any forward-looking statement as a result of new information, future events or otherwise, except as may be required by law.

**Company Contact:** Steve Kunszabo  
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