

WARNER CHILCOTT PLC

FORM 8-K

(Current report filing)

Filed 07/16/10 for the Period Ending 07/16/10

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

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

Form 8-K

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

Date of Report: July 16, 2010
Date of earliest event reported: July 16, 2010

Warner Chilcott Public Limited Company

(Exact name of registrant as specified in its charter)

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)

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 July 16, 2010, Warner Chilcott Public Limited Company (the “Company”) issued a press release announcing its receipt of a communication from the U.S. Food & Drug Administration (“FDA”) related to its next generation Actonel[®] (risedronate sodium) delayed-release tablets extending the Prescription Drug User Fee Act (“PDUFA”) date by three months to allow sufficient time to review additional information solicited by the FDA and previously provided by the Company. The new PDUFA date is October 24, 2010.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 Press Release issued July 16, 2010

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: July 16, 2010

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued July 16, 2010



NEWS RELEASE

**Warner Chilcott Announces 3-Month Extension of PDUFA Date on
Next Generation Actonel Product**

ARDEE, Ireland, July 16, 2010—Warner Chilcott plc (NASDAQ: WCRX) announced today that it has received a communication from the U.S. Food & Drug Administration (FDA) related to its next generation Actonel[®] product (risedronate sodium) delayed-release tablets extending the Prescription Drug User Fee Act (PDUFA) date by three months to allow sufficient time to review additional information solicited by the FDA and previously provided by the Company. The new PDUFA date is October 24, 2010.

The Company

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 a fully integrated company 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 economic 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" 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 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 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 the PGP Acquisition; 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.

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