

WARNER CHILCOTT PLC

FORM 8-K (Current report filing)

Filed 10/14/10 for the Period Ending 10/11/10

Telephone	353 41 685 6983
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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: October 14, 2010
Date of earliest event reported: October 11, 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*FDA Approval of Atelvia™*

On October 11, 2010, Warner Chilcott Public Limited Company (the “Company”) issued a press release announcing that the U.S. Food & Drug Administration had approved its next generation ACTONEL® (risedronate sodium) product for the treatment of postmenopausal osteoporosis in the United States, which will be marketed as ATELVIA™ (risedronate sodium) delayed-release tablets.

Lupin Settlement

On October 14, 2010, the Company issued a press release announcing that the Company and its subsidiary, Warner Chilcott Company, LLC, and Lupin Ltd. and its subsidiary, Lupin Pharmaceuticals, Inc., have entered into a settlement agreement to resolve pending patent litigations involving the Company’s oral contraceptive products, Loestrin® 24 Fe and Femcon® Fe.

Item 9.01 Financial Statements and Exhibits*(d) Exhibits .*

99.1 Press Release issued October 11, 2010

99.2 Press Release issued October 14, 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/ Paul Herendeen

Name: Paul Herendeen

Title: Executive Vice President and Chief Financial Officer

Date: October 14, 2010

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued October 11, 2010
99.2	Press Release issued October 14, 2010

**NEWS RELEASE****Warner Chilcott Announces FDA Approval of Next Generation Actonel**

ARDEE, Ireland, October 11, 2010 – Warner Chilcott plc (NASDAQ: WCRX) today announced that the United States Food and Drug Administration (FDA) has approved its next generation ACTONEL[®] (risedronate sodium) product for the treatment of postmenopausal osteoporosis in the United States. The product will be marketed as ATELVIA[™] (risedronate sodium) delayed-release tablets.

“The approval of ATELVIA represents an exciting addition to the ACTONEL franchise, as well as our women’s healthcare product portfolio. We believe the dosing convenience of ATELVIA sets it apart from other treatment options for osteoporosis patients and provides an opportunity to regain market share in the U.S. in this segment,” said Roger Boissonneault, President and CEO of Warner Chilcott.

The Company anticipates the commercial launch of ATELVIA in early 2011.

About ATELVIA

ATELVIA is a bisphosphonate in a delayed-release formulation and is indicated for treatment of postmenopausal osteoporosis. For information on dosage and administration, contraindications, warnings and precautions, adverse reactions, and other important safety and other prescribing information, please see http://www.wcrx.com/pdfs/pi/pi_atelvia.pdf.

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 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” 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, including increases in the LIBOR rates on our variable-rate indebtedness above the applicable floor amounts; 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: Rochelle Fuhrmann
Investor Relations
973-442-3281
rfuhrmann@wcrx.com

**NEWS RELEASE****Warner Chilcott Announces Settlement with Lupin of
Loestrin[®] 24 Fe and Femcon[®] Fe Patent Litigations**

ARDEE, Ireland, October 14, 2010 – Warner Chilcott plc (NASDAQ: WCRX) and its subsidiary, Warner Chilcott Company, LLC, and Lupin Ltd. and its subsidiary, Lupin Pharmaceuticals, Inc., today announced that they have entered into a settlement agreement to resolve pending patent litigations involving Warner Chilcott’s oral contraceptive products, Loestrin[®] 24 Fe and Femcon[®] Fe (the “Settlement Agreement”).

Under the terms of the Settlement Agreement, Lupin has agreed that, except in the event of an at-risk launch by a third-party of a generic Loestrin[®] 24 Fe product, neither Lupin nor its affiliates will market or sell a generic Loestrin[®] 24 Fe product prior to July 22, 2014. In the event of such an at-risk launch by Lupin, Warner Chilcott has reserved its right to bring an infringement suit against Lupin and pursue all legally available remedies. In addition, Warner Chilcott has granted Lupin a non-exclusive license covering Femcon[®] Fe, which will permit Lupin to commence marketing either an authorized generic product, which would be supplied by Warner Chilcott, or generic equivalent of Femcon[®] Fe in the United States beginning on the earlier of (1) 180 days after the date that Teva Pharmaceutical Industries, Ltd enters the market with a generic equivalent to Femcon[®] Fe, or (2) January 1, 2013.

Warner Chilcott has also granted Lupin the rights to purchase and sell in the United States an authorized generic version of the Asacol[®] 400 mg product, which would be supplied by Warner Chilcott, only if a generic version of the Asacol[®] 400 mg product is launched by a third party in the United States.

The final settlement remains subject to certain conditions specified in the Settlement Agreement, including the Court’s ordering the stipulations of dismissal.

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