WARNER CHILCOTT LTD

FORM 8-K
(Current report filing)

Filed 01/16/09 for the Period Ending 01/16/09

Telephone	441-295-2244
CIK	0001323854
Symbol	WCRX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

http://www.edgar-online.com
© Copyright 2009, EDGAR Online, Inc. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.

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: January 16, 2009
Date of earliest event reported: January 16, 2009

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

Bermuda	1 – 33039	98-0496358
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Gibbons Building, 10 Queen Street, Suite 109-1st Floor
Hamilton HM11, Bermuda
(Address of principal executive offices, including zip code)

(441) 292-0068
(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))

Item 7.01 Regulation FD Disclosure.

On January 16, 2009, Warner Chilcott Limited (the "Company") announced that one of its subsidiaries and Mayne Pharma International Pty. Ltd. ("Mayne"), a subsidiary of Hospira, Inc., have filed a lawsuit against Sandoz Inc. in the District Court for the District of New Jersey for infringement of Mayne's U.S. Patent No. 6,958,161 which covers DORYX, a tetracycline-class oral antibiotic. A copy of the Company's press release is filed as Exhibit 99.1 hereto and is incorporated by reference into this Item 7.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release issued January 16, 2009.

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 L IMITED

By: /s/ Paul Herendeen
Name: Paul Herendeen
Title: Executive Vice President and Chief Financial Officer

Date: January 16, 2009

Exhibit 99.1

Warner Chilcott files new lawsuit for Infringement of DORYX® Patent

Hamilton, Bermuda - January 16, 2009. Warner Chilcott Limited (Nasdaq: WCRX) announced today that one of its subsidiaries and Mayne Pharma International Pty. Ltd. ("Mayne"), a subsidiary of Hospira, Inc., have filed a lawsuit against Sandoz Inc. ("Sandoz") in the District Court for the District of New Jersey for infringement of Mayne's U.S. Patent No. 6,958,161 (the "'161 Patent") which covers DORYX, a tetracycline-class oral antibiotic. Warner Chilcott markets and sells DORYX delayed-release tablets in 150, 100 and 75 mg strengths under a license agreement with Mayne. Warner Chilcott previously announced the filing of similar lawsuits against each of Mutual Pharmaceutical Company, Inc., Mylan Pharmaceuticals Inc. and Impax Laboratories, Inc. on December 23, 2008.

The lawsuit is in response to the submission of an Abbreviated New Drug Application ("ANDAs") to the U.S. Food and Drug Administration ("FDA") by Sandoz requesting approval to manufacture and sell generic versions of DORYX 100 and 75 mg delayed-release tablets prior to the expiration in 2022 of the '161 Patent. Warner Chilcott and Mayne intend to vigorously defend the '161 Patent and pursue their legal rights.

About Warner Chilcott

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare and dermatology segments of the U.S. pharmaceuticals market. The Company is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. WCRX-G.

Read more on www.warnerchilcott.com .

Company Contact: Rochelle Fuhrmann
Investor Relations
973-442-3281
rfuhrmann@wcrx.com

Warner Chilcott's Forward Looking Statements:

This press release contains forward-looking statements, including statements concerning our 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 facility to 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 facility; 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; the other risks identified in our Annual Report on Form 10-K for the year ended December 31, 2007; and other risks detailed from time-to-time in our public filings, financial statements and 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.