

SHIRE PLC

FORM 8-K (Current report filing)

Filed 07/08/10 for the Period Ending 07/08/10

Telephone	441256894000
CIK	0000936402
Symbol	SHPGF
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

Item 8.01. Other Events

Shire plc has issued the press release attached hereto as Exhibit 99.01 which is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is filed herewith:

99.01 Press Release dated July 8, 2010

SIGNATURE

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.

SHIRE PLC

By: /s/ A C Russell
Name: Angus Russell
Title: Chief Executive Officer

Dated: July 8, 2010

EXHIBIT INDEX

Number	Description
99.01	Press Release dated July 8, 2010

Press Release



www.shire.com

Lialda[®] - Shire Files Suit against Cadila Healthcare Limited, doing business as Zydus Cadila and Zydus Pharmaceuticals (USA), Inc.

Dublin, Ireland and Philadelphia, US – July 8, 2010 – Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, announces that its subsidiaries Shire Development Inc. and Shire Pharmaceutical Development Inc. have filed a lawsuit in the U.S. District Court for the District of Delaware against Cadila Healthcare Limited, doing business as Zydus Cadila and Zydus Pharmaceuticals (USA), Inc. (collectively “Zydus”) for the infringement of U.S. Patent No. 6,773,720 (the ‘720 patent).

The lawsuit was filed as a result of an Abbreviated New Drug Application (ANDA) filed by Zydus seeking FDA approval to market and sell generic versions of Lialda[®] (mesalamine) prior to the expiration of the ‘720 patent.

Under the Hatch-Waxman Act, because Shire filed its patent infringement lawsuit within 45 days of receiving the Paragraph IV notification letter from Zydus, the FDA must refrain from approving Zydus’ ANDA for 30 months, or until a district court decision finding that the patent is invalid or not infringed, whichever occurs earlier. The stay on generic approval will expire in November 2012 unless terminated earlier.

For further information please contact:

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Notes to editors

SHIRE PLC

Shire’s strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit hyperactivity disorder (ADHD), human genetic therapies (HGT) and gastrointestinal (GI) diseases as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire’s in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company’s website: www.shire.com.

"SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included herein that are not historical facts are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, the Company's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of research, development, approval, reimbursement, manufacturing and commercialization of the Company's Specialty Pharmaceutical and Human Genetic Therapies products, as well as the ability to secure and integrate new products for commercialization and/or development; government regulation of the Company's products; the Company's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on the Company's products; the Company's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; the Company's ability to obtain and maintain government and other third-party reimbursement for its products; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission.
