

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

SHIRE PHARMACEUTICALS GROUP PLC

CIK: **936402** | IRS No.: **000000000** | Fiscal Year End: **1231**
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| Mailing Address | Business Address |
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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 (Date of earliest event reported): August 12, 2004

Shire Pharmaceuticals Group plc

(Exact name of registrant as specified in its charter)

England and Wales

(State or other jurisdiction of incorporation)

0-29630
(Commission File Number)

98-0359573
(IRS Employer Identification No.)

Hampshire International Business Park, Chineham, Basingstoke,
Hampshire RG24 8EP England

(Address of principal executive offices)

(Zip code)

Registrant's telephone number, including area code

44 1256 894 000

(Former name or former address, if changed since last report)

Item 5. Other Events

Shire Pharmaceuticals Group plc has issued the press release attached as Exhibit 99.1 and which is incorporated by reference herein.

Item 7. Financial Statements and Exhibits

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

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 PHARMACEUTICALS GROUP
PLC**

By: /s/ A C Russell _____

Name: Angus Russell

Title: Chief Financial Officer

Dated: August 12, 2004

EXHIBIT INDEX

| Number | Description |
|--------|-------------------------------------|
| 99.1 | Press Release dated August 12, 2004 |

Shire Pharmaceuticals Group plc
Hampshire International Business Park,
Chineham, Basingstoke RG24 8EP UK
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<http://www.shire.com>

EXHIBIT 99.1



For immediate release
(07.00am BST) (02.00am EST)

US FOOD & DRUG ADMINISTRATION (FDA) APPROVES ADDERALL XR® TO TREAT ADULTS

Basingstoke, UK and Philadelphia, PA, US - August 12, 2004 - Shire Pharmaceuticals Group plc (LSE: SHP, NASDAQ: SHPGY, TSX: SHQ) announces that its leading treatment for Attention Deficit Hyperactivity Disorder (ADHD), ADDERALL XR® (mixed salts of a single-entity amphetamine) has been approved by the US FDA as a once-daily treatment for adults.

ADDERALL XR net sales for the 6 months to June 2004 were US \$283 million, 30% up on the same period in 2003.

Shire will begin promoting the adult indication in the US immediately.

In addition, the FDA has confirmed to Shire that new 40mg, 50mg and 60mg dose strengths of ADDERALL XR will require additional clinical data for approval.

Shire Chief Executive, Matthew Emmens commented:

"ADDERALL XR® is the most prescribed brand for the treatment of ADHD in the US*, a market that expanded by 20% over last year. The impact of ADHD on people's ability to carry out their daily lives and work effectively is being increasingly acknowledged and the market for adult patients could ultimately be double that for pediatric patients. Although we have not been able to promote adult usage, many physicians have been prescribing ADDERALL XR for adults 'off label' for some time. Adults represent 15 - 20% of the current ADDERALL XR total prescriptions. We can now support the expansion of this adult market segment."

Studies have shown that up to 65 percent of children with ADHD continue to exhibit symptoms into adulthood and an estimated 4.4 percent of the U.S. adult population is affected by ADHD.ⁱ If left untreated, this disorder may lead to other psychological difficulties, such as depression, as well as occupational and social disability.ⁱⁱ Appropriate diagnosis and treatment of ADHD in adults helps improve self-esteem, work performance and skills, educational attainment and social competencies.ⁱⁱⁱ Over 8 million adults in the U.S. may exhibit the symptoms of ADHD, while only an estimated 600,000 are being treated.

Dr Richard H. Weisler, adjunct Professor of Psychiatry at the University of North Carolina, Chapel Hill (UNC) School of Medicine and principal investigator for ADDERALL XR studies in adults, commented:

"ADHD in adult patients may significantly impair a person's social and family relationships, as well as his or her career. Stimulant therapies, such as ADDERALL XR, have been used successfully in

patients for more than 60 years. It's an important step that ADDERALL XR is the first stimulant to be approved for use in adults."

For further information please contact:

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Notes to editors

Shire Pharmaceuticals Group plc

Shire Pharmaceuticals Group plc (Shire) is a global specialty pharmaceutical company with a strategic focus on meeting the needs of the specialist physician and currently focuses on developing projects and marketing products in the areas of central nervous system (CNS), gastrointestinal (GI), and renal diseases. Shire has operations in the world's key pharmaceutical markets (US, Canada, UK, France, Italy, Spain and Germany) as well as a specialist drug delivery unit in the US.

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

ABOUT ADDERALL XR

ADDERALL XR is a once-daily extended release, single-entity amphetamine product available in 5mg, 10mg, 15mg, 20mg, 25mg and 30mg. The ADDERALL XR capsule contains two types of drug-containing beads designed to give a double-pulsed delivery of amphetamines, which prolongs the release of amphetamine from ADDERALL XR compared to the conventional ADDERALL® (immediate-release) tablet formulation.

The US FDA approved ADDERALL XR in November 2001 for the treatment of ADHD in children.

THE "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, Shire's results could be materially affected. The risks and uncertainties include, but are not limited to, risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing and commercialization, the impact of competitive products, including, but not limited to, the impact on Shire's Attention Deficit & Hyperactivity Disorder (ADHD) franchise, patents, including but not limited to, legal challenges relating to Shire's ADHD franchise, government regulation and approval, including but not limited to the expected product approval dates of lanthanum carbonate (FOSRENOL®), methylphenidate (METHYPATCH®), anagrelide hydrochloride (XAGRID®), carbamazepine (BIPOTROL®) and mesalamine (PENTASA® 500mg), the implementation of the planned reorganization and other risks and uncertainties detailed from time to time in Shire's filings with the Securities and Exchange Commission.

SOURCE/REFERENCES

* IMS data w/e 30/07/04: ADDERALL XR had a 23.02% market share

ⁱ Kessler, R., et al. Prevalence of Adult ADHD in the United States: Results from the National Comorbidity Survey Replication (NCS). Presented at the American Psychiatric Association meeting. May 1, 2004; New York, NY.

ⁱⁱ RoperASW. Living with ADHD: A National Survey of People With Attention Deficit Hyperactivity Disorder. Study presented at Annual Meeting of American Psychiatric Association. May 6, 2004. New York, NY.

