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FORM 10-Q

Shire plc - N/A

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Quarterly report with a continuing view of a company's financial position

NPS EX. 2127
CFAD v. NPS
IPR2015-00990

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549
FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period ended March 31, 2015**

Commission File Number: 0-29630

SHIRE PLC

(Exact name of registrant as specified in its charter)

Jersey (Channel Islands)
(State or other jurisdiction of incorporation or organization)

98-0601486
(I.R.S. Employer Identification No.)

**5 Riverwalk, Citywest Business Campus, Dublin 24, Republic of
Ireland**
(Address of principal executive offices and zip code)

+353 1 429 7700
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (232,405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As at April 24, 2015 the number of outstanding ordinary shares of the Registrant was 600,292,756.

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 adversely affected. The risks and uncertainties include, but are not limited to, that:

- Shire’s products may not be a commercial success;
- product sales from ADDERALL XR and INTUNIV are subject to generic competition;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for Shire’s products may affect future revenues, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its products and is reliant on third party contract manufacturers to manufacture other products and to provide goods and services. Some of Shire’s products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of Shire’s products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis for some period of time;
- the manufacture of Shire’s products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- Shire has a portfolio of products in various stages of research and development. The successful development of these products is highly uncertain and requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval;
- the actions of certain customers could affect Shire’s ability to sell or market products profitably. Fluctuations in buying or distribution patterns by such customers can adversely affect Shire’s revenues, financial condition or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire’s activities in the highly regulated markets in which it operates may result in significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire’s ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire’s revenues, financial condition or results of operations;
- Shire faces intense competition for highly qualified personnel from other companies and organizations. Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect Shire’s ability to attract and/or retain the highly skilled personnel needed for Shire to meet its strategic objectives;
- failure to achieve Shire’s strategic objectives with respect to the acquisition of NPS Pharmaceuticals Inc. (“NPS Pharma”) may adversely affect Shire’s financial condition and results of operations; and

other risks and uncertainties detailed from time to time in Shire’s filings with the Securities and Exchange Commission, including those risks outlined in “Item 1A: Risk Factors” in Shire’s Annual Report on Form 10-K for the year ended December 31, 2014.

The following are trademarks either owned or licensed by Shire plc or its subsidiaries, which are the subject of trademark registrations in certain territories, or which are owned by third parties as indicated and referred to in this Form 10-Q:

ADDERALL XR® (mixed salts of a single entity amphetamine)
AGRYLIN® (anagrelide hydrochloride)
BUCCOLAM® (midazolam hydrochloride oromucosal solution)
CALCICHEW® (trademark of Takeda Nycomed AS)
CARBATROL® (carbamazepine extended-release capsules)
CEREZYME® (trademark of Genzyme)
CINRYZE® (C1 esterase inhibitor [human])
DAYTRANA® (trademark of Noven Pharmaceutical Inc. ("Noven"))
DERMAGRAFT® (trademark of Organogenesis Inc. ("Organogenesis"))
ELAPRASE® (idursulfase)
ELVANSE® (lisdexamfetamine dimesylate)
ELVANSE ADULT® (lisdexamfetamine dimesylate)
ELVANSE VUXEN® (lisdexamfetamine dimesylate)
ESTRACE® (trademark of Trimel Pharmaceuticals Inc.)
EQUASYM® (methylphenidate hydrochloride)
EQUASYM XL® (methylphenidate hydrochloride)
FIRAZYR® (icatibant)
FOSRENOL® (lanthanum carbonate)
GATTEX® (teduglutide [rDNA origin])
INTUNIV® (guanfacine extended release)
LIALDA® (trademark of Nogra International Limited)
MEZAVANT® (trademark of Giuliani International Limited)
MIMPARA® (cinacalcet HCl)
NATPAR® (parathyroid hormone)
NATPARA® (parathyroid hormone (rDNA))
PENTASA® (trademark of Ferring B.V. Corp ("Ferring"))
PLENADREN® (hydrocortisone, modified release tablet)
PREMIPLEX® (IGF-I/IGFBP-3)
REGPARA® (cinacalcet HCl)
REPLAGAL® (agalsidase alfa)
RESOLOR® (prucalopride)
REVESTIVE® (teduglutide)
SENSIPAR® (cinacalcet HCl)
TYVENSE® (lisdexamfetamine dimesylate)
VASCUGEL® (allogeneic aortic endothelial cells cultured in a porcine gelatin matrix [Gelfoam®] with cytokines, implanted)
VANCOCIN® (trademark of ANI Pharmaceuticals Inc.)
VENVANSE® (lisdexamfetamine dimesylate)
VPRIV® (velaglucerase alfa)
VYVANSE® (lisdexamfetamine dimesylate)
XAGRID® (anagrelide hydrochloride)
ZEFFIX® (trademark of GSK)
3TC® (trademark of GSK)

SHIRE PLC
Form 10-Q for the three months to March 31, 2015

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