

SMITH & NEPHEW PLC
Form 6-K
October 14, 2014

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of
1934

October 13, 2014

Commission File Number 001-14978

SMITH & NEPHEW plc
(Registrant's name)

15 Adam Street
London, England WC2N 6LA
(Address of registrant's principal executive offices)

[Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.]

| | |
|---|------------------------------------|
| Form 20-F <input checked="" type="checkbox"/> | Form 40-F <input type="checkbox"/> |
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[Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1).]

| | |
|------------------------------|--|
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| --- | --- |

[Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7).]

| | |
|------------------------------|--|
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| --- | --- |

[Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing information to the Commission pursuant to Rule 12g3-2 (b) under the Securities Exchange Act of 1934.]

| | |
|------------------------------|--|
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
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If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2 (b) : 82- n/a.

Smith & Nephew announces top-line results of HP802-247 Phase 3 study

13 October 2014

Smith & Nephew (LSE: SN, NYSE: SNN), the global medical technology business, announces top-line results from a Phase 3 study of HP802-247, a living cell spray-on therapy designed to work with the body's own cells to stimulate healing of venous leg ulcers ("VLUs"). HP802-247 did not meet the primary endpoint, namely a statistically significant improvement in healing over placebo, in a randomized, double-blind, vehicle-controlled study in North America.

The result reported today is headline data. A full analysis of the efficacy data and study methodology is underway and will be completed in the coming months. A second Phase 3 study in the European Union, which is expected to report in 2016, will continue while the programme analysis is completed.

Olivier Bohuon, Chief Executive Officer of Smith & Nephew, commented:

"A thorough assessment is underway to determine why the preliminary results of the first Phase 3 study are inconsistent with the strongly positive Phase 2a/2b results. While this is an unexpected and disappointing development with this one product, we remain excited by the prospects for advanced wound bioactives as unique treatments for unmet patient needs."

Background to the study

HP802-247 is an allogenic living cell bio-formulation of irradiated keratinocytes and fibroblasts in a human fibrin suspension.

In June 2011 HP802-247 delivered positive data from a Phase 2b clinical trial, demonstrating that the compound met both its primary and secondary endpoints in the treatment of VLUs. The compound entered Phase 3 trials for this indication in North America in September 2012.

The North American study measured complete wound closure over a 12-week period in patients treated with HP802-247 plus standard care compression versus treatment with placebo plus compression. It was a randomized, double-blind study involving subjects 18 years of age and older with VLUs of at least six weeks but not more than 24 months duration.

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Enquiries

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About Smith & Nephew

Smith & Nephew is a global medical technology business dedicated to helping healthcare professionals improve people's lives. With leadership positions in Orthopaedic Reconstruction, Advanced Wound Management, Sports Medicine and Trauma & Extremities, Smith & Nephew has around 14,000 employees and a presence in more than 90 countries. Annual sales in 2013 were more than \$4.3 billion. Smith & Nephew is a member of the FTSE100 (LSE: SN, NYSE: SNN).

For more information about Smith & Nephew, please visit our corporate website www.smith-nephew.com, follow @SmithNephewplc on Twitter or visit SmithNephewplc on Facebook.com

Forward-looking Statements

This document may contain forward-looking statements that may or may not prove accurate. For example, statements regarding expected revenue growth and trading margins, market trends and our product pipeline are forward-looking statements. Phrases such as "aim", "plan", "intend", "anticipate", "well-placed", "believe", "estimate", "expect", "target", "consider" and similar expressions are generally intended to identify forward-looking statements.

Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from what is expressed or implied by the statements. For Smith & Nephew, these factors include: economic and financial conditions in the markets we serve, especially those affecting health care providers, payers and customers; price levels for established and innovative medical devices; developments in medical technology; regulatory approvals, reimbursement decisions or other government actions; product defects or recalls; litigation relating to patent or other claims; legal compliance risks and related investigative, remedial or enforcement actions; strategic actions, including acquisitions and dispositions, our success in performing due diligence, valuing and integrating acquired businesses; disruption that may result from transactions or other changes we make in our business plans or organisation to adapt to market developments; and numerous other matters that affect us or our markets, including those of a political, economic, business, competitive or reputational nature. Please refer to the documents that Smith & Nephew has filed with the U.S. Securities and Exchange Commission under the U.S. Securities Exchange Act of 1934, as amended, including Smith & Nephew's most recent annual report on Form 20-F, for a discussion of certain of these factors. Any forward-looking statement is based on information available to Smith & Nephew as of the date of the statement. All written or oral forward-looking statements attributable to Smith & Nephew are qualified by this caution. Smith & Nephew does not undertake any obligation to update or revise any forward-looking statement to reflect any change in circumstances or in Smith & Nephew's expectations.

◇ Trademark of Smith & Nephew. Certain marks registered US Patent and Trademark Office.

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 thereunto duly authorized.

Smith & Nephew Plc
(Registrant)

Date: October 13, 2014

By: /s/ Susan Swabey

Susan Swabey
Company Secretary
