SMITH & NEPHEW PLC Form 20-F March 27, 2009 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

- " REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934 or
- x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2008

or

- " TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 or
- " SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 Commission file number 0-19003

Smith & Nephew plc

(Exact name of Registrant as specified in its charter)

England and Wales

(Jurisdiction of incorporation or organization)

15 Adam Street, London WC2N 6LA

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class American Depositary Shares Name on each exchange on which registered New York Stock Exchange

Ordinary Shares of 20¢ each

New York Stock Exchange*

Securities registered or to be registered pursuant to Section 12(g) of the Act: None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None.

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report: 949,890,174 Ordinary Shares of 20¢ each

Indicate by check mark if the registrant is a well seasoned issuer, as defined in Rule 405 of the Securities Act Yes x No "

If this Report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 Yes "No x

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 (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes x No "

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

^{*}Not for trading, but only in connection with the registration of American Depositary Shares, pursuant to the requirements of the Securities and Exchange Commission.

Large Accelerated Filer x Accelerated Filer " Non-accelerated filer "

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing.

"U.S. GAAP x International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If Other has been checked to the previous question indicate by check mark which financial statement item the registrant has elected to follow: Item 17 " Item 18 "

If this is an annual report, indicated by check mark whether the registrant is a shell company (as defined in Rule

12b-2 of the Exchange Act). Yes " No x

INTRODUCTION AND FINANCIAL SUMMARY

The Smith & Nephew Group (the Group) is a global medical devices business operating in the orthopaedics, endoscopy and advanced wound management markets with revenue of approximately \$3.8 billion in 2008. Smith & Nephew plc is the parent company of the Smith & Nephew Group. It is an English public limited company with its shares listed on the official list of the UK Listing Authority and it is traded on the London Stock Exchange and on the New York Stock Exchange in the form of American Depositary Shares (ADSs).

This report is the Annual Report of Smith & Nephew plc for the year ended 31 December 2008. It comprises in a single document the Annual Report and Accounts of the company in accordance with UK requirements and the Annual Report on Form 20-F in accordance with the regulations of the Securities and Exchange Commission in the US.

A summary report on the year, the Summary Financial Statement 2008, intended for the investor who does not require the full detail of the Annual Report is available on Smith & Nephew s corporate website at www.smith-nephew.com/investors along with the electronic version of this Annual Report. The Summary Financial Statement includes a summary remuneration report and summary financial statements.

The Group s fiscal year end is 31 December. References in this Annual Report to a particular year are to the fiscal year unless otherwise indicated. Except as the context otherwise requires, Ordinary Share or share refer to the Ordinary Shares of Smith & Nephew plc of US 20¢ each.

For the convenience of the reader, a Glossary of technical and financial terms used in this document is included on page 164. The product names referred to in this document are identified by the use of capital letters and are trademarks owned by or licensed to members of the Smith & Nephew Group.

Key Performance Indicators

The Report of the Directors includes a number of measures that management uses as key performance indicators. Underlying growth in revenue is not presented in the accounts prepared in accordance with IFRS and is therefore not a Generally Accepted Accounting Principle (non-GAAP) measure. The principal key performance indicators presented in the Annual Report are:

Underlying growth in revenue

Underlying growth in revenue is a non-GAAP financial measure which is a key performance indicator used by the Group's management in order to compare the revenue in a given year to that of the previous year on a like-for-like basis. This is achieved by adjusting for the impact both of sales of products acquired in business combinations and for movements in exchange rates. An explanation of how this non-GAAP measure is calculated is presented in the Business Overview on page 28.

The Group believes that the tabular presentation and reconciliation of revenue growth from reported to underlying assists investors in their assessment of the Group s performance in each business segment and for the Group as a whole.

Underlying growth in revenue is considered by the Group to be an important measure of performance in terms of local functional currency since it excludes those items considered to be outside the influence of local management. The Group's management uses this non-GAAP measure in its internal financial reporting, budgeting and planning to assess performance on both a business segment and a consolidated Group basis. Revenue growth at constant currency is important in measuring business performance compared to competitors and compared to the growth of the market itself. The Group's annual bonus incentive plans include an element which relates to revenue growth performance. Targets are set and performance measured in constant currency excluding the step-change impact of acquisitions.

The Group considers that the revenue from sales of products acquired in business combinations results in a step-up in growth in revenue in the year of acquisition that cannot be wholly attributed to local management s efforts with respect to the business in the year of acquisition. Depending on the timing of the acquisition there will usually be a further step change in the following year. A measure of growth excluding the effects of business combinations also allows senior management to evaluate the performance and relative impact of growth from the existing business and growth from acquisitions. The process of making business acquisitions is directed, approved and funded from the Group corporate centre in line with strategic objectives.

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The material limitation of the underlying growth in revenue measure is that it excludes certain factors, described on page (i), which ultimately have a significant impact on total revenues. The Group compensates for this limitation by taking into account relative movements in exchange rates in its investment, strategic planning and resource allocation. In addition, as the evaluation and assessment of business acquisitions is not within the control of local management, performance of acquisitions is monitored centrally until the business is integrated. The Group s management considers that both the non-GAAP measure of underlying growth in revenue and the GAAP measure of growth in revenue are complementary measures neither of which management use exclusively.

Basic adjusted earnings per ordinary share (EPSA), trading profit and adjusted attributable profit

Growth in EPSA and trading profit are measures which present the trend growth in the long-term profitability of the Group excluding the impact of specific transactions or events that management considers affect the Group s short-term profitability. The Group presents these measures to assist investors in their understanding of trends. EPSA growth and trading profit are also the key measures used for remunerating senior management in order to align the interests of senior management with those of investors. The Group s internal financial reporting (budgets, monthly reporting, forecasts, long-term planning and incentive plans), focuses primarily on profit and earnings before these items.

The Group has identified the following items, where material, as those to be adjusted and identified separately: acquisition and disposal related items including amortisation and impairment of acquisition intangible assets; significant restructuring events; gains and losses arising from legal disputes and uninsured losses; and taxation thereon. A reconciliation of attributable profit to adjusted attributable profit, which represents the numerator used in the EPSA calculation, is presented in Selected Financial Data on page 155. An explanation of how trading profit is calculated is presented in Business Overview on page 28.

EPSA and trading profit are not recognised measures under IFRS. The material limitation of these measures is that they exclude significant income and costs that have a direct impact on current and prior years—profit attributable to shareholders. They do not, therefore, measure the overall performance of the Group presented by the GAAP measures of earnings per share and operating profit. The Group considers that no single measure enables it to assess overall performance and therefore it compensates for the limitation of the adjusted earnings per share and trading profit measures by considering them in conjunction with their GAAP equivalents. Gains or losses which are identified separately arise from irregular events or transactions. Such events or transactions are authorised centrally and require a strategic assessment which includes consideration of financial returns and generation of shareholder value. Amortisation of acquisition intangibles will occur each year, whilst other excluded items arise irregularly depending on the events that give rise to such items.

Presentation

The results of the Group, as reported in US Dollars, are affected by movements in exchange rates between US Dollars and other currencies. The Group applied the average exchange rates prevailing during the year to translate the results of non-US companies into US Dollars. The currencies which most influenced these translations in the years covered by this report were Sterling, Swiss Franc and the Euro.

The Group Accounts of Smith & Nephew in this Annual Report are presented in US Dollars. Solely for the convenience of the reader, certain parts of this Annual Report contain translations of amounts in US Dollars into Sterling at specified rates. These translations should not be construed as representations that the US Dollar amounts actually represent such Sterling amounts or could be converted into Sterling at the rate indicated. Except as where stated otherwise, the translation of US Dollars and cents to Sterling and pence appearing in this Annual Report has been made at the noon buying rate in The City of New York for cable transfers in Sterling as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate) on the

date indicated. On 11 March 2009, the Noon Buying Rate was US\$1.38 per £1.

The Accounts of the Group in this Annual Report are presented in millions (m) unless otherwise indicated.

Smith & Nephew s corporate website, <u>www.smith-nephew.com</u>, gives additional information on the Group. Information made available on the website is not intended to be, and should not be regarded as being, part of this Annual Report.

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Financial Summary

Financial Highlights

	2008 \$ million	2007 \$ million
Revenue	3,801	3,369
Trading profit	776	706
Operating profit	630	493
Attributable profit for the year	377	316
Adjusted attributable profit	493	480
Basic earnings per Ordinary Share	42.6¢	34.2¢
Basic EPSA	55.6¢	52.0¢
Dividends per Ordinary Share (i)	13.08¢	11.89¢

⁽i) The Board has declared a second interim dividend of 8.12¢ per share which together with the first interim dividend of 4.96¢ makes a total for 2008 of 13.08¢. The second interim dividend will be paid on 8 May 2009 to shareholders on the Register of Members at the close of business on 17 April 2009.

Special Note Regarding Forward-Looking Statements

The Group s reports filed with, or furnished to, the US Securities and Exchange Commission (SEC), including this document and written information released, or oral statements made, to the public in the future by or on behalf of the Group, constitute forward-looking statements within the meaning of the US Private Securities Litigation Reform Act of 1995. In particular, statements regarding planned growth in the Group s business and trading margins discussed under Outlook and Trend Information are forward-looking statements as are discussions of the Group s product pipeline and discussions of the costs of future revisions of the macrotextured knee product under Recent Developments, Legal Proceedings and Operating and Financial Review Liquidity and Prospects. When used in this Annual Report, the words aim, anticipate, believe, consider, estimate, expect, intend, plan, target, well-placed and similar expressions are generally intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors (including, but not limited to, the outcome of litigation and regulatory approvals) that could cause the actual results, performance or achievements of Smith & Nephew, or industry results, to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Specific risks faced by the Group are described under Risk Factors on page 22 of this Annual Report.

All forward-looking statements in this Annual Report are based on information available to Smith & Nephew as of 17 March 2009. All written and oral forward-looking statements attributable to Smith & Nephew or any person acting on behalf of Smith & Nephew are expressly qualified in their entirety by the foregoing. Smith & Nephew does not undertake any obligation to update or revise any forward-looking statement contained herein to reflect any change in Smith & Nephew s expectation with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Market Data

Market data and market share estimates throughout this report are derived from a variety of sources including publicly available competitors information, internal management information and independent market research reports.

Documents on Display

It is possible to read and copy documents referred to in this Annual Report at the Registered Office of the Company. Documents referred to in this Annual Report that have been filed with the Securities and Exchange Commission in the US may be read and copied at the SEC s public reference room located at 450 Fifth Street, NW, Washington DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms and their copy charges. The SEC also maintains a web site at www.sec.gov that contains reports and other information regarding registrants that file electronically with the SEC. This Annual Report and some of the other information submitted by the Group to the SEC may be accessed through the SEC website.

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This Annual Report including the Report of the Directors was approved by the Board of Directors on 17 March 2009.

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⁽i) A discussion of the Group s Key Performance Indicators is given in Introduction and Financial Summary on pages i and ii.

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DESCRIPTION OF THE GROUP

This section discusses the activities, resources and operating environment of the business under the following headings:

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Discussion of the Group s management structure and corporate governance procedures is set out in the Corporate Governance section (pages 51 to 61).

The Remuneration Report gives details of the Group s policies on senior management s remuneration in 2008 (pages 63 to 72).

Discussion of the Group s operating and financial performance, liquidity and financial resources for 2008 and 2007 is given in the Operating and Financial Review, Liquidity and Prospects (pages 27 to 49).

Details of the structure of the Company s share capital and securities, persons with significant shareholdings in the Company and a summary of the Memorandum and Articles of association are incorporated into the Directors Report and are given in Investor Information (pages 147 to 167).

THE BUSINESS

HISTORY AND DEVELOPMENT

Group Strategy

Smith & Nephew is a global business engaged in the development, manufacture, marketing and sales of medical devices in the sectors of orthopaedics (which includes reconstruction, trauma and clinical therapies), endoscopy and advanced wound management.

Group History

The Group has a history dating back 153 years to the family enterprise of Thomas James Smith who opened a small pharmacy in Hull, England in 1856. On his death in 1896, his nephew Horatio Nelson Smith took over the management of the business. Smith & Nephew was incorporated and listed on the London Stock Exchange in 1937. Today it is a public limited company incorporated in the UK, registered in, and conducted under the laws of, England and Wales. The corporate headquarters is in the UK. Operations in countries other than the UK are under the laws of those countries. In November 1999, the Group was listed on the New York Stock Exchange.

In 2001, Smith & Nephew became a constituent member of the FTSE-100 index in the UK. This means that Smith & Nephew is included in the top 100 companies traded on the London Stock Exchange measured in terms of market capitalisation.

Recent Developments

The Reconstruction and Trauma and Clinical Therapies segments reported separately in the annual accounts of the Group for the year ended 31 December 2007 are now combined into a single reporting segment named Orthopaedics for the year ended 31 December 2008. This reflects the unification of the management reporting structure for these businesses announced during the year. Where relevant, revenue, trading profit and operating profit comparative figures have been restated.

During 2008, a dedicated Biologics business was formed, bringing together the research programmes and skills from across the Group, focusing on advanced locally delivered biological therapies to promote healing and pain relief.

In February 2007, the Group commenced a share buy-back programme of up to \$1.5 billion over an initial two years. In 2008, 16 million shares were purchased at a total cost of \$193m. Since the programme began, the Group has purchased 68 million shares at a cost of \$833m. In light of the current conditions in the financial markets, the Group announced in November 2008 to suspend the share buy-back programme. There has been no change in the Group s long-term target balance sheet, cash generation or acquisition policy. The programme will remain under review going forward.

On 27 September 2007, settlements were reached in respect of the subpoenas issued by the US Attorney for the District of New Jersey's office to the Group's Orthopaedics business in 2005 and four of its primary competitors. The Group paid a civil restitution payment of \$29m and entered into a Deferred Prosecution Agreement and Corporate Integrity Agreement which required improvements to its compliance program. See Legal Proceedings (pages 47 to 48).

On 31 May 2007, the Group completed the purchase of Plus Orthopedics Holding AG (Plus) a private Swiss orthopaedic company for a total of CHF1,086m (\$889m) in cash, including assumed debt. The acquisition was financed by bank borrowings and was integrated into the Group's Orthopaedics business. The acquisition of Plus increased the Group's share of the global orthopaedics market, making it the fourth largest global orthopaedics reconstruction company.

In January 2009, the Group reached an agreement with the vendors of Plus to reduce the total original purchase price by CHF159m. As part of the agreement the parties resolved their disputes on the contractual purchase price adjustments. In addition, the Group released the vendors from substantially all of their warranties, including those relating to taxation, under the original purchase agreement and dropped all existing claims under the original warranties.

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On 10 May 2007, the Group purchased BlueSky Medical Group, Inc., (BlueSky), a private US company for an initial payment of \$15m with further milestone payments of up to \$95m related to revenues and other events. The company developed products for treating chronic wounds using negative pressure wound therapy and markets a range of negative pressure pumps and wound dressing kits. BlueSky has been integrated into the Group s Advanced Wound Management business.

Following a group-wide in-depth review, the Group launched an Earnings Improvement Programme (EIP) during the first quarter of 2007. The objectives of the programme were to enhance short and medium term performance, to liberate resources for investment and to establish a culture of continuous improvement. Workstreams were created to address improved performance, mainly in the following areas of the Group s business:

in cost of goods by increased use of lower-cost locations, mainly in Asia, and savings in procurement by taking advantage of opportunities on a Group wide basis;

in a number of administration functions by centralising, where appropriate, functions formerly run separately by each business, for example, Information Systems and Human Resources;

in marketing by exploring opportunities to rationalise the Group s product portfolio; and

in sales functions by optimising the structure, deployment and efficiency of sales forces and sales channels.

The financial objectives of the EIP are to contribute to an increase in trading profit margin by an average of 1% per annum to the end of 2010, net of a planned increase in research and development expenditure. Cash restructuring costs are estimated to be \$125m spread over three years to 2010.

BUSINESS DESCRIPTION

Organisation

Smith & Nephew operates on a worldwide basis. This has been achieved through a series of acquisitions, in the US and in Europe, and through continued emphasis on the development and introduction of new products in the Group s principal markets.

Smith & Nephew is currently organised into three global business units of Orthopaedics (which includes Reconstruction, Trauma and Clinical Therapies), Endoscopy and Advanced Wound Management. The Group also has a separate emerging markets unit. In 21 of the 32 countries in which the Group operates, the global business units take direct responsibility for business operations. These are referred to as direct markets. The remaining markets in which the Group has operations are managed by country managers, who are responsible for sales and distribution of the Group s product range, and comprise the emerging markets unit.

A head office team in London, England directs the overall business and supports the business units, primarily in the areas of business development, legal, company secretarial, finance, human resources and investor relations. A dedicated Biologics

business located in York, England and Durham, North Carolina brings together the research programmes and skills from across the Group, focusing on advanced, locally delivered biological therapies to promote healing and pain relief.

Orthopaedics

Overview

Orthopaedics comprises reconstruction, trauma and clinical therapies products.

Orthopaedic reconstruction implants include hip, knee and shoulder joints as well as ancillary products such as bone cement and mixing systems used in cemented reconstruction joint surgery. Orthopaedic trauma fixation products consist of internal and external devices and orthobiological materials used in the stabilisation of severe fractures and deformity correction procedures. Clinical therapies products are those that are applied in an orthopaedic office or clinic setting and include bone growth stimulation, joint fluid therapies and outpatient spine products.

The Orthopaedics business is managed worldwide from Memphis, Tennessee, which is also the site of its main manufacturing facility. Products are also manufactured at smaller facilities in Switzerland, Germany, and the UK

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as well as third-party manufacturers. The Clinical Therapies business is headquartered in Durham, North Carolina, and also maintains operations in Memphis, Tennessee.

The Total Knee product portfolio includes the LEGION Total Knee System and the JOURNEY family of products. The LEGION Total Knee System is comprehensive and technologically advanced. It enables a surgeon to move from a simple primary procedure to a difficult revision procedure with a single surgical technique philosophy. VERILAST is one of the newest technologies offered as part of the LEGION System. It is the combination of OXINIUM and XLPE and provides and maintains extremely low wear rates. The JOURNEY family includes a range of products developed for the active patient. The JOURNEY BCS Knee System is designed by the Group to reproduce normal kinematics. Other highlights of the Group s early intervention portfolio include the new JOURNEY Uni System, the JOURNEY PFJ, and the JOURNEY DEUCE implants. VISIONAIRE is a key new technology spanning the Group s total knee portfolio that includes the development of patient specific cutting blocks with the goal of improved outcomes, less surgical complications, and shorter surgical time.

The trauma fixation product portfolio consists of internal and external devices used in the stabilisation of many types of fractures and limb deformity correction procedures. Internal fixation products, such as the TRIGEN INTERTAN Intertrochanteric Nail, the PERI-LOC upper and lower locked plating systems, PERI-LOC VLP and external fixation systems such as JET-X and TAYLOR SPATIAL FRAME provide orthopaedic surgeons with a comprehensive offering of products to address trauma and deformity correction procedures.

Smith & Nephew integrated Plus into its worldwide business during 2008. The Plus Gliding Nail and IP-XS trauma products were added to the Group s European business. The Plus spine business consists of internal spinal fixation products sold in certain European countries. The majority of the products are sourced through a distribution agreement with a third party. Smith & Nephew plans to continue to maintain this spinal fixation business and will evaluate opportunities for future growth in this market segment.

The EXOGEN line of ultrasonic bone healing stimulators, DUROLANE and SUPARTZ hyaluronic acid joint fluid therapies, and outpatient spine products, are the main products in the clinical therapies portfolio. EXOGEN retained its number one market share position for long bone stimulation in 2008. EXOGEN is an ultrasound technology approved to treat fractures that have failed to heal (known as non-unions) and in some cases prescribed to help specific fresh fractures heal faster. DUROLANE is a single injection therapy used to treat osteoarthritis of the knee and hip (currently only approved in Europe and Canada), and is manufactured by Q-MED AB of Sweden. SUPARTZ is an injection therapy used to treat osteoarthritis of the knee, and is manufactured by Seikagaku Corporation of Japan.

Strategy

Smith & Nephew s strategy for the reconstruction market is to become the leading innovator of solutions for the active, informed patient. Management believes that by focusing innovation on the needs of younger, more active patients, Smith & Nephew can lead the sector in providing hip and knee implants to this growing demographic segment. For example, in the US, patients aged 64 and under represent 41% of the primary hip and knee replacement market, and management believes this segment is growing at twice the overall market rate. The Orthopaedics business continues to invest in strategies that drive patient demand through integrated communications programs, including direct-to-consumer advertising, public relations and internet-based initiatives.

Smith & Nephew s strategy for the trauma and clinical therapies markets is to deliver growth through innovative product development in its existing core business while expanding into fast-growing market areas including alternative therapies for pain management and fracture healing. Management believes these markets will continue to grow for the foreseeable future. This is largely attributable to a global population increasingly at risk from fractures due to age, osteoporosis, obesity and diabetes, and to continuous advancements in the surgical treatment of fractures. Smith & Nephew intends to further penetrate these markets by expanding its sales force and by introducing less invasive therapies. The Group is also contributing to patient education and empowerment through its websites, traditional medical education and cadaveric training of residents and attending surgeons.

New Products

In 2008, for the reconstruction market, Orthopaedics launched the R3 Acetabular System, supporting XLPE, metal and ceramic liners in a single cup system, giving the surgeon all advanced bearing options without changing implants intraoperatively. Also launched was VERILAST technology, introduced this year with the LEGION family of knee products. VERILAST couples XLPE with the Group s proprietary OXINIUM technology to reduce wear rates while maintaining superior femoral and tibial integrity.

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In the trauma market, several significant product innovations were commercialised in 2008. The polyaxial locking mechanism of the PERI-LOC Variable-Angle Locked Plating System (VLP) allows the angles at which locking screws can be inserted and locked into any of the low profile plates to be adjusted for optimal intraoperative versatility. PERI-LOC VLP specifically targets partial articular fractures in areas of the body where implant prominence and soft-tissue irritation are major concerns. Additionally, the PERI-LOC Periarticular Reduction Forceps Set provides a variety of soft-tissue sparing instruments for percutaneous reduction of fractures prior to definitive fixation. The Large Cannulated Screw System (6.5mm, 7.0mm and 8.0mm) offers new implants and enhanced instrumentation for percutaneous and/or open fracture fixation using cannulated screws. The PERI-LOC PFP (proximal femoral plate) presents an alternative to traditional femoral plating with locked plating technology. The TRIGEN META-NAIL Blocking Screw Instruments allow precision placement of blocking screws during intramedullary nail procedures to assist with fracture reduction, nail insertion, and postoperative implant stability. The TRIGEN Percutaneous Intertrochanteric/Femoral Antegrade Nail Instruments facilitate minimally invasive antegrade femoral nailing procedures and optimise intraoperative efficiency by combining all proximal locking options into a single intuitive radiolucent drill guide drop.

Recent Regulatory Approvals

In February 2008, the Japanese government approved the use of the OXINIUM technology in the GENESIS II Knee System in Japan. Regulatory teams in Memphis and Tokyo had been seeking approval for OXINIUM femoral components in the Japanese market for more than six years. Approval of OXINIUM technology will allow additional OXINIUM implant products to be registered in Japan and will eventually give Japanese customers access to the company s complete hip and knee portfolios.

In 2008, US approvals for the R3 Acetabular Shell and Metal Liner for use with BHR and BHR manufacturing site change were received. US clearance was obtained for fifteen products: MIS Hip Stem; JET-X Bar System Quick Clamp Bar and Post, MR Conditional; INTERTAN Compression Hip Screw; PERI-LOC Volar Distal Radius Plate; Ti ECHELON Hip Stem; SL-PLUS Hip Stem; PIGALILEO 4th Generation Surgical Navigation System; MDF Revision Hip Stem; JOURNEY Uni Femoral Component; LEGION Hinge Knee; OXINIUM DH Femoral Head; PERI-LOC Hexalobular Bone Screw; PROMOS Reverse Shoulder; PIGALILEO Surgical Navigation System Knee Replacement Software Module; and VISIONAIRE Patient Matched Cutting Blocks.

Competition

Management estimates that the worldwide orthopaedic market (excluding clinical therapies) served by the Group grew by approximately 8% in 2008 and is currently worth more than \$15.5 billion per annum. Management believes that Smith & Nephew holds a 12% share of this market by value. Principal global competitors in the orthopaedic market are Zimmer, Stryker, DePuy/Johnson & Johnson, Synthes and Biomet.

Management estimates that the worldwide market for clinical therapies increased by 5% in 2008 and is currently worth more than \$1.6 billion per annum. Smith & Nephew s primary market for clinical therapies is in the US. In the US long bone stimulation market management estimates Smith & Nephew s market share to be 41%. Principal competitors are Biomet, DJ Ortho and Orthofix. In the US joint fluid therapies market Smith & Nephew maintains a share of 21%. The principal competitors are Genzyme, Sanofi Aventis, DePuy/Johnson & Johnson and Ferring Pharmaceuticals.

Endoscopy

Overview

Smith & Nephew s Endoscopy business, headquartered in Andover, Massachusetts, develops and commercialises endoscopic (minimally invasive surgery) techniques, educational programmes and value-added services for surgeons to treat and repair soft tissue and articulating joints. The business focuses on the arthroscopy sector of the endoscopy market. Arthroscopy is the minimally invasive surgery of joints, in particular the knee, shoulder and hip.

The Endoscopy business offers surgeons endoscopic technologies for surgery, including: specialised devices and fixation systems to repair damaged tissue; fluid management and insufflation equipment for surgical access; digital cameras, digital image capture, scopes, light sources and monitors to assist with visualisation; and radiofrequency wands, electromechanical and mechanical blades, and hand instruments for resecting damaged tissue.

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Manufacturing facilities are currently located in Mansfield, Massachusetts, Oklahoma City, Oklahoma and San Antonio, Texas. Major service centres are located in the US, the UK, Germany, Japan and Australia.

Strategy

Smith & Nephew s strategic intent is to maintain and grow the business as the leading provider of endoscopic techniques and technologies for joint and ligament repair. Management believes that the business capitalises on the growing acceptance of endoscopy as a preferred surgical choice among physicians, patients and customers.

To sustain growth and enhance its market position, the Endoscopy business supports its strategy with surgeon education programmes, financing solutions, global fellowship support initiatives, partnerships with professional associations and surgeon advisory boards.

New Products

In 2008, Smith & Nephew continued to expand its arthroscopic repair portfolio with the launch of the FOOTPRINT PK Suture Anchor, a system used to attach rotator cuff tissue to bone in the shoulder.

Additionally, the BIORAPTOR 2.3 PK Suture Anchor was launched for repair of instability in both the shoulder and hip joints. This anchor is designed to be implanted in the dense bone along the rim of the joint socket. Its small size and design provide strong fixation, and enable a surgeon to use more than one to establish multiple attachment points. Its delivery system also enables a surgeon to insert it directly through an incision in the skin rather than through a cannula.

Smith & Nephew s new CROSSTRAC Hip Guide and ARTHROGARDE Hip Access Cannula systems were launched in 2008. They are designed to ensure more consistent and accurate minimally invasive pathways for the diagnosis and repair of injuries in the hip joint.

The business also launched its BIOSURE HA Interference Screw line for use in reconstructing the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) in the knee. BIOSURE Interference screw can be used to secure the tibial or femoral end of an ACL or PCL graft.

Recent Regulatory Approvals

During 2008, the Endoscopy business obtained regulatory clearances for the following products in most major markets, except Japan where the approval process is more lengthy: BIOSURE HA bioabsorbable interference screw, made with poly-L-lactic acid (PLLA) and Hydroxyapatite (HA); FOOTPRINT PK suture anchor for shoulder rotator cuff repair; OSTEORAPTOR suture anchor for shoulder instability repair, featuring PLLA with HA; and various other arthroscopy instruments and devices. In addition, the business also gained approval in Japan for the BioRCI bioabsorbable interference screw.

Competition

Management estimates that the global arthroscopy market in which the business principally participates is worth more than \$2.5 billion a year and is growing at 12% annually, driven by increasing numbers of sports injuries, longer and more active lifestyles, patient desire for minimally invasive procedures, innovative technological developments and a need for cost effective procedures. Management believes that Smith & Nephew has a 23% share of the global arthroscopy market.

Smith & Nephew s main competitors in the global arthroscopy market in 2008 were Arthrex, Mitek/Johnson & Johnson, Stryker, Arthrocare and Linvatec/Conmed.

Advanced Wound Management

Overview

Smith & Nephew s Advanced Wound Management business has its global headquarters in Hull, England and its North American headquarters in St Petersburg, Florida. The business offers a range of products from initial wound bed preparation through to full wound closure. These products are targeted at chronic wounds connected with the older population, such as pressure sores and venous leg ulcers, and the alleviation of wounds such as burns and invasive surgery that impact the wider population.

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Advanced Wound Management products are manufactured at facilities in Hull and Gilberdyke, England; Largo, Florida; and by certain third party manufacturers around the world.

Strategy

The strategy for the Advanced Wound Management business is to focus on the higher added value segments of exudate and infection management through improved wound bed preparation and moist and active healing. In 2007 the business entered the negative pressure wound therapy (NPWT) market with the acquisition of BlueSky, which management believes will allow the business to build further presence in the technologically advanced areas of advanced wound management.

The Advanced Wound Management business has built its sales and marketing infrastructure in the world s major markets, largely through investment in additional sales teams particularly in the key markets of the US and Europe.

In 2007 and 2008, management has taken part in the Group-wide EIP and reviewed cost and efficiency across the Advanced Wound Management business. Savings have been delivered in 2007 and 2008 in areas ranging from support functions to the outsourcing of some manufacturing to low cost countries. In 2007 the business announced the planned closure of the Largo, Florida manufacturing facility. A manufacturing facility in Suzhou, China is currently being built for opening in 2009.

New Products

Management believes that the market will continue the trend towards advanced products with their ability to accelerate healing rates, reduce hospital stay times and cut the cost of clinician and nursing time and aftercare in the home.

The move into the NPWT market, particularly in the US, provides access to a market place that management estimates is worth \$1.4billion in annual revenue and to a range of products that management believes can deliver a sophisticated medium using negative pressure to enhance wound healing.

The ALLEVYN hydrocellular dressings range has been considerably enhanced by new versions introduced in recent years that management believes deliver efficient fluid management and an optimal moist wound environment that can lead to promotion of faster healing of the wound, reduced risk of maceration and protection from infection. During 2008, the ALLEVYN range was extended further with the development of variants that included soft gel adhesives. This new range of dressings has the efficient fluid management capability of the existing ALLEVYN dressings whilst improving comfort and reducing pain on removal for the patient.

The ACTICOAT range was enhanced during 2008 with the launch of ACTICOAT Flex, a conformable range of dressings designed to address wounds in awkward anatomical areas such as face and hands and to improve patient comfort during wear. The ACTICOAT range incorporates the smallest crystallised silver (nanocrystalline silver) used in the treatment of wounds or burns. The silver reduces the risk of bacterial colonisation and acts to kill micro-organisms that can cause infection and prevent or retard healing.

Recent Regulatory Approvals

During 2008, the Advanced Wound Management business secured approvals for a new variant of ALLEVYN Heel, which includes the addition of silver, for ACTICOAT Flex and for low friction Flexigrid. In addition the Group secured European approval for BIOSTEP, a denatured collagen dressing designed to stimulate tissue granulation. In Japan there have been eight product approvals including ALLEVYN Lite, a thinner version of the ALLEVYN range.

Competition

Management estimates that the sales value of the advanced wound management market worldwide was \$5.2 billion in 2008, an increase of 7% from 2007 which includes the impact of the continuing expansion of the NPWT segment. Management estimates that Smith & Nephew has a 17% market share of the wider market. Growth is driven by an ageing population and by a steady advance in technology and products that are more clinically efficient and cost effective than their conventional counterparts. Management believes that there is strong growth potential for advanced technology products.

Worldwide competitors in advanced wound management in 2008 include Kinetic Concepts, who are wholly in the NPWT segment, Convatec, Mölnlycke and Systagenix, the former Johnson & Johnson wound care business.

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Joint Ventures and Discontinued Operations

Joint ventures are those in which the Group holds an interest on a long-term basis and which are jointly controlled by the Group and one other entity under a contractual agreement.

Discontinued operations in 2006 represent the gain on disposal of the Group s joint venture, BSN Medical. Smith & Nephew owned 50% of the BSN Medical joint venture, which was jointly owned with Beiersdorf AG and was independently managed. BSN Medical comprised traditional woundcare, fracture casting and bandaging and compression hosiery businesses. Following the Group s announcement in August 2005 of its intention to dispose of BSN Medical, Smith & Nephew and Beiersdorf AG announced in December 2005 that they had signed an agreement to sell BSN Medical to Montagu Private Equity for an enterprise value of 1,030m. This transaction was completed on 23 February 2006.

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OPERATING ACTIVITIES

SALES, MARKETING AND DISTRIBUTION

Smith & Nephew s customers are the various providers of medical and surgical services worldwide. In certain parts of the world, including the UK, much of Continental Europe, Canada and Japan, these are largely government organisations funded by tax revenues. In the US, the Group s major customers are public and private hospitals, which receive revenue from private health insurance and government reimbursement programmes. In the US, Medicare is the major source of reimbursement for knee and hip reconstruction procedures and for wound healing treatment regimes.

Competition exists among healthcare providers to gain patients on the basis of quality, service and price. In many countries, providers are under pressure to reduce the total cost of healthcare delivery. There has been some consolidation in the Group s customer base, as well as amongst the Group s competitors, and these trends are expected to continue in the long term. Smith & Nephew competes against both specialised and multinational corporations, including those with greater financial, marketing and other resources.

The Group s customers reflect the wide range of distribution channels, purchasing agents and buying entities in over 90 countries worldwide. The largest single customers worldwide are the National Health Service in the UK and HealthTrust in the US which represented 4% and 2% respectively of the Group s worldwide revenue in 2008.

In the US, the Group s products are marketed directly to doctors, hospitals and other healthcare facilities with each business unit operating a separate specialised sales force. The US sales forces consist of a mixture of independent commissioned sales agents and direct employees. The independent agents are not permitted contractually to sell products that compete with Smith & Nephew s. Orthopaedics and Endoscopy products are shipped and invoiced directly to the ultimate customer. Advanced Wound Management products are marketed directly to the ultimate customer. However, the products are shipped and invoiced to a number of wholesale distributors. In most other direct markets, the business units typically manage employee sales forces directly.

The emerging markets unit comprises direct selling and marketing operations in India, China, Hong Kong, Korea, Malaysia, Singapore, Thailand, the United Arab Emirates, South Africa, Mexico and Puerto Rico. In these markets, Orthopaedics and Endoscopy frequently share sales resources. The Advanced Wound Management sales force is typically separate because it calls on different customers. In other countries, Smith & Nephew sells to third party distributors which market the Group s products locally.

The Group operates a number of central distribution facilities in the key geographical areas in which it operates. Orthopaedics and Endoscopy operate a facility in Baar, Switzerland which acts as the main holding and consolidation point for markets outside of the US. Hubs serving the US are located in Memphis for Orthopaedics and Oklahoma for Endoscopy. Product is shipped to Group companies who hold small amounts of inventory locally for immediate or urgent customer requirements. Advanced Wound Management distribution hubs include Neunkirchen, Germany; Nottingham, UK; and Atlanta, US.

SEASONALITY

Smith & Nephew s revenues are generally at their highest in the fourth quarter of any year. This is caused by the relatively high number of accidents and sports injuries which occur in the North American and European autumn and winter seasons which increase revenues of orthopaedic trauma and endoscopy products. Orthopaedic reconstruction revenues are lower in the third quarter due to fewer elective surgeries in the summer and higher in the fourth quarter as elective surgeries increase.

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MANUFACTURE AND SUPPLY

Where management considers that the Group possesses a core competence, its policy is to manufacture products internally whenever possible to ensure quality, regulatory and cost goals are met. The Group invests in the expansion of its manufacturing facilities and equipment to meet these aims. The Group will outsource manufacturing where a need is identified. This might include a requirement for specialised expertise, lower costs of production or capacity constraints.

Where products and services are outsourced, suppliers are determined based on a number of factors which include the complexity of the product, manufacturing technology, manufacturing capabilities, cost competitiveness and intellectual property. Suppliers are selected based on their capability to deliver products and services to specification, their ability to establish and maintain a quality system and their financial stability. Suppliers are monitored through on-site assessments and ongoing monitoring of delivered products. Ongoing product assurance is maintained by effective quality plans.

Each business unit purchases raw materials, components, finished products and packaging materials from certain key suppliers. These principally include metal forgings and stampings for Orthopaedics, optical and electronic sub-components and finished goods for Endoscopy, active ingredients and finished goods for Advanced Wound Management and packaging materials across all businesses. Management believe that whilst prices of principal raw materials can be volatile, the effect is not material to the Group. Finished goods purchased for resale include SUPARTZ joint and DUROLANE fluid therapy products in the Orthopaedics business, screen displays, optical and electrical devices in the Endoscopy business and enzyme debrider agents and ACTICOAT in the Advanced Wound Management business.

PROPERTY, PLANT AND EQUIPMENT

The Group s principal locations are as follows:

	, .pp. 0,
	area
	(Square feet
	000 s)
Group head office in London, England	15
Group research facility in York, England	88
Orthopaedics headquarters and manufacturing facilities in Memphis, Tennessee	770
Orthopaedics distribution facility in Memphis, Tennessee (i)	102
Orthopaedics distribution facility in Memphis, Tennessee (new facility)	210
Orthopaedics manufacturing facility in Aarau, Switzerland	77
Orthopaedics European headquarters in Rotkreuz, Switzerland (i)	28
Orthopaedics manufacturing in Beijing, China	20
Orthopaedics and Endoscopy distribution facility in Baar, Switzerland	50
Endoscopy headquarters in Andover, Massachusetts	112
Endoscopy manufacturing facility in Mansfield, Massachusetts	98
Endoscopy manufacturing and distribution facility in Oklahoma City, Oklahoma	150

Annroximate

Advanced Wound Management headquarters and manufacturing facility in Hull, England	439
Advanced Wound Management manufacturing facility in Gilberdyke, England	41
Advanced Wound Management manufacturing facility in Suzhou, China	128
Advanced Wound Management manufacturing facility in Largo, Florida (i)	135
Advanced Wound Management US headquarters in St. Petersburg, Florida	40
Biologics headquarters in Durham, North Carolina	27

(i) It has been announced these facilities will close in 2009.

The Orthopaedics headquarters and manufacturing facilities in Memphis, the facilities in Aarau and the Advanced Wound Management facilities in Hull, Gilberdyke, and Largo are freehold while all other principal locations are leasehold. In 2008, improved Orthopaedics distribution facilities were opened in Baar (leasehold) and Memphis (freehold). Advanced Wound Management are nearing completion on their manufacturing facility in Suzhou which is leasehold. The Group has freehold and leasehold interests in real estate in other countries throughout the world, but no other is individually significant to the Group. Where required, the appropriate governmental authorities have approved the facilities. During 2008 a dedicated Biologics business was formed, which is headquartered in Durham, North Carolina.

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As part of the EIP programme, the Group announced its intention to close the Largo manufacturing facility in 2009 and to outsource or relocate its manufacturing output. The Advanced Wound Management business purchased land in Suzhou, China and is building a new facility to supply certain wound management products on a global basis. The Orthopaedics business has purchased land near Beijing, China and construction is due to start on a new facility to supply implants to the local market and orthopaedic instruments for export.

RESEARCH AND DEVELOPMENT

The business units each manage a portfolio of short and long-term product development projects designed to meet the future needs of their customers and continue to provide growth opportunities for their businesses. The Group 's research and development is directed towards all three business segments. Expenditure on research and development amounted to \$152m in 2008 (2007 \$142m, 2006 \$120m), representing approximately 4% of Group revenue (2007 4%, 2006 4%).

The Group s principal research facility is located in York, England with research programmes that seek to underpin the longer-term technology requirements for its businesses and to provide a flow of innovative products. The Group continues to invest in future technology opportunities, particularly active biologic solutions for clinical needs identified from across the Smith & Nephew businesses. In-house research is supplemented by work performed by academic institutions and other external research organisations in Europe, America and Asia.

Product development is carried out at the Group s principal locations, notably in Memphis, Tennessee and Aarau, Switzerland (Orthopaedics), Mansfield, Massachusetts (Endoscopy) and Hull, England (Advanced Wound Management).

INTELLECTUAL PROPERTY