RISK FACTORS

This section describes some of the risks that could affect the Group’s businesses. The factors below should be considered in connection with any forward-looking statements in this Form 20-F and the cautionary statements contained in the “Introduction” on page 2.

Smith & Nephew’s products are not in life support activities and in general are unlikely to threaten life. But, if they malfunctioned, they could damage or impair the repair of body functions. Management believes that the Group’s quality, regulatory and medical controls and insurance activities are adequate and appropriate for this class of products. The Company’s reputation is crucially dependent on strong performance in this area and on appropriate crisis management if a serious medical incident or product recall should occur.

The Board of Directors of Smith & Nephew is responsible for the maintenance of the Group’s systems of risk management and internal control and for reviewing their effectiveness. An ongoing process has been in place for the full year identifying, evaluating and managing key risks through a Risk Committee, that comprises GEC members, which reports to the Board of Directors annually, and by a system of functional reports to the Board of Directors and the review of internal financial controls by the Audit Committee. These procedures are designed to identify and manage those risks that could adversely impact the achievement of the Group’s objectives. While they do not provide absolute assurance against material misstatements or loss, the Directors, following a review of the systems described, are of the opinion that proper systems of risk management and internal control are in place within the Group.

The Group is insured against product, employers’ and directors’ and officers’ liabilities and physical and consequential loss, subject to limits and deductibles. The Group maintains liability reserves to cover known uninsured risks.

The risks below are not the only ones that the Group faces. Some risks are not yet known to the Group and some risks that the Group does not currently believe to be material could later turn out to be material. All of these risks could materially affect the Group’s business, its revenues, operating income, net assets, liquidity and resources.

The Group is reliant on the effective implementation of its strategy

The Group may encounter market conditions or other challenges to the implementation of its strategy that could result in the Group not meeting its shareholders’ expectations of income or growth.

The Group is reliant on new technology

The Group operates in the medical device industry, which has a rapid introduction rate of new products. There is a risk to sales growth unless sufficient new products are introduced to the market place in a timely manner. There is also a risk of product (and in certain cases associated facilities) obsolescence.

New products developed and marketed by competitors may affect price levels in the Group’s markets and may result in products being replaced over time. The Group’s ability to develop and market new products acceptable to the market place is a key factor in maintaining its competitive position.

The Group is dependent on trends in healthcare expenditure

Changes in healthcare policy by governments or reimbursement authorities in major countries around the world can result in changes to the revenues of one or more of the Group’s product lines. The Group is also dependent on the continued growth in surgical procedures.

The Group is exposed to product liability and patent infringement claims

Because of the nature of the Group’s business, it is subject to a relatively high risk of product liability claims. The Group maintains product liability insurance, but this insurance is subject to limits and deductibles. In addition, insurance premiums are relatively high, particularly for US coverage, and there is a risk, at the industry level, of coverage becoming increasingly costly. The Group is also exposed to the potential for patent infringement claims, particularly because of the technological nature of medical devices.

The Group is exposed to risk of competitor consolidation

The markets in which the Group operates each contain a number of different major international competitors. The merger or consolidation of two or more of these competitors could impact the Group’s strategic position.

The Group is exposed to regulatory approvals and controls

The medical device industry is highly regulated. Regulatory requirements are a major factor in determining whether substances and materials can be developed into marketable products and the amount of time and expense that should be allotted to such development. At any time the Group is awaiting a number of regulatory approvals, which if not received, could adversely affect results of operations.

The Group is exposed to political, economic and currency fluctuations

Because the Group has operations in many countries, political and economic developments in those countries or in the regions surrounding those countries may impact the Group’s results of operation. Terrorist activities and ongoing global political uncertainties, including conflict in the Middle East, could adversely impact the Group. In addition, political changes in a country could prevent the Group from receiving remittances of profit from a member of the Group located in that country or from selling its investments in that country. Fluctuations in interest rates and currency exchange rates particularly between sterling and the US dollar and between the currencies in which its international operations or investments operate, could adversely affect the Group’s earnings and the value of these businesses. Also, see the discussion of exchange and interest rate risk in “Item 5—Operating and Financial Review and Prospects”.

The Group is exposed to credit risk arising from financial instruments

The Group is subject to credit risk on cash, deposits and derivative instruments in the event of the non-performance of its counterparties.

The Group is dependent upon recruiting and retaining key personnel

In order to develop, support and market the products offered by the Group, it is necessary to hire and retain highly skilled employees with particular expertise. The implementation of the Group’s strategic business plans could be undermined by failure to recruit or retain key personnel.

The Group is reliant on its reputation

An event that materially damaged the reputation of the Group or one or more of the its brands could have an adverse impact on subsequent revenues.

The Group is reliant on certain suppliers

The Group is reliant on certain key suppliers of raw materials; forgings and stampings for orthopaedics, optical and electronic subcomponents for endoscopy and active ingredients and products for advanced wound management. If these suppliers were unable to supply, there could be an adverse effect on the Group’s results.

The Group is reliant on eight main manufacturing facilities

The Group has manufacturing production concentrated at eight main facilities in Memphis, Tennessee, Andover and Mansfield, Massachusetts, Oklahoma City, Oklahoma, Palo Alto and La Jolla, California and Largo, Florida in the United States and Hull in the United Kingdom for its businesses of orthopaedics, endoscopy and advanced wound management. If major physical disruption took place at any of these sites, it would adversely affect the results of operations. Physical loss and consequential loss insurance is carried to cover such risks subject to limits and deductibles.

The Group is dependent upon successfully integrating any businesses that it acquires

The Group has in the past and expects to pursue in the future acquisitions or alliances to complement its existing businesses. These types of transactions involve numerous risks, including successfully integrating acquired businesses, any of which could adversely affect the Group’s results.

The Group is exposed to the risk that the investment values of its pension plans may not eventually be sufficient to meet pension obligations

The Group has two major defined benefit pension plans that are funded by investment assets. To the extent that pension liabilities and investment returns accrue at rates different to those presently assumed, unplanned funding obligations could occur.

ITEM 4—INFORMATION ON THE COMPANY

HISTORY AND DEVELOPMENT OF THE COMPANY

Group Overview

Smith & Nephew is a global company that concentrates on the development and marketing of medical devices in the three growth sectors of orthopaedics, endoscopy and advanced wound management. These three businesses comprise the Group’s “Ongoing Operations” segment.

The Group’s activities have a history dating back 147 years to the family enterprise of Thomas James Smith who opened a small drugstore in Hull, England in 1856. On his death in 1896, his nephew Horatio Nelson Smith took over the management of the business. The Company is a public limited company incorporated in Great Britain registered in, and operating under the laws of, England and Wales. Operations undertaken in countries other than the United Kingdom are under the laws of those countries in which they reside. The Company was incorporated and listed on the London Stock Exchange in 1937. In November 1999, the Company was listed on the New York Stock Exchange. The corporate headquarters is in the United Kingdom and the registered address is:

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Information contained on our website is not intended to be, and should not be regarded as being, part of this annual report on Form 20-F.

In June 2001, Smith & Nephew became a constituent part of the FTSE 100 index in the United Kingdom. This means that the Group is included in the top 100 companies traded on the London Stock Exchange measured in terms of market capitalization.

Recent Developments

In January 2000, Smith & Nephew acquired the collagenase advanced woundcare business from BASF Pharma for £74 million. Results of this acquisition are reflected in Ongoing Operations from the date of acquisition.

In June 2000, Smith & Nephew sold its consumer healthcare business for a net cash consideration of £210 million.

In April 2001, Smith & Nephew transferred its casting and bandaging and traditional woundcare businesses to a 50/50 joint venture with Beiersdorf AG, known as BSN Medical. Results of the businesses contributed to the joint venture by Smith & Nephew prior to April 1, 2001 are reflected in “Operations contributed to the joint venture” within “Continuing operations”. Beginning April 1, 2001, Smith & Nephew accounted for the results of the joint venture using the gross equity method.

In April 2001, Smith & Nephew acquired the advanced woundcare business of Beiersdorf AG for £30 million. Results of this business are reflected in Ongoing Operations commencing from the date of acquisition.

In May 2001, Smith & Nephew acquired the anti-microbial woundcare business of Westaim BioMedical Corporation for an initial consideration of £12 million. Results of this acquisition are reflected in Ongoing Operations from the date of acquisition.

In June 2001, Smith & Nephew sold its ear, nose and throat business for a net cash consideration of £62 million to Gyrus plc. This business is classified in the Group’s profit and loss accounts as Discontinued.

In March 2002, Smith & Nephew disposed of its rehabilitation business to AbilityOne Corporation (“AbilityOne”), a leading supplier in the US of rehabilitation products to hospitals, nursing homes and clinics, doing business as SammonsPreston. Smith & Nephew received £71 million in cash and a 21.5% equity interest in the combined company. Results of this business are classified as Discontinued. Beginning April 1, 2002, Smith & Nephew’s equity interest in AbilityOne was accounted for using the net equity method.