SMITH & NEPHEW PLC
Form 6-K
March 04, 2019

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

March 04, 2019

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 X Form 40-F
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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 No X
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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)(7).]

Yes No X
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[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 No X
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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.

4 March 2019

Smith & Nephew plc (the "Company")
Annual Financial Report

The following documents have today been posted or otherwise made available to shareholders:

1. 2018 Annual Report

2. Notice of 2019 Annual General Meeting ("AGM")

3. Form of Proxy for the 2019 AGM

In accordance with Listing Rule 9.6.1 a copy of each of these documents has been uploaded to the National Storage Mechanism and will be available for viewing shortly at http://www.morningstar.co.uk/uk/NSM. The 2018 Annual Report on Form 20-F was filed with the SEC earlier today.

Documents are also available on the Company's website at www.smith-nephew.com/annualreport2018 and www.smith-nephew.com/AGM, in hard copy to shareholders and ADS holders and free of charge, upon request to Corporate Affairs, Smith & Nephew plc, 15 Adam Street, London WC2N 6LA.

Compliance with Disclosure and Transparency Rule 6.3.5 ("DTR 6.3.5") - Extracts from the 2018 Annual Report

The information below, which is extracted from the 2018 Annual Report, is included solely for the purpose of complying with DTR 6.3.5 and the requirements it imposes on how to make public, Annual Financial Reports. It should be read in conjunction with the Company's Press Release issued on 7 February 2019 (available at www.smith-nephew.com/investor-centre/). Together these constitute the material required by DTR 6.3.5 to be communicated to the media in unedited full text through a Regulatory Information Service. This material is not a substitute for reading the full 2018 Annual Report. All page numbers and cross-references in the extracted information below refer to page numbers in the 2018 Annual Report.

The information contained in this announcement and in the Press Release does not constitute the Group's statutory accounts, but is derived from those statutory accounts. The statutory accounts for the year ended 31 December 2018 have been approved by the Board and will be delivered to the Registrar of Companies following the Company's AGM. The auditor has reported on those statutory accounts and their report was unqualified, with no matters by way

of emphasis, and did not contain statements under Section 498(2) of the Companies Act 2006 (regarding adequacy of accounting records and returns) or under Section 498(3) of the Companies Act 2006 (regarding provision of necessary information and explanations).

Appendix A - Risk factors

RISK FACTORS

There are known and unknown risks and uncertainties relating to Smith & Nephew's business. The factors listed on pages 188-191 could cause the Group's business, financial position and results of operations to differ materially and adversely from expected and historical levels. In addition, other factors not listed here that Smith & Nephew cannot presently identify or does not believe to be equally significant could also materially adversely affect Smith & Nephew's business, financial position or results of operations.

Highly competitive markets

The Group competes across a diverse range of geographic and product markets. Each market in which the Group operates contains a number of different competitors, including specialised and international corporations. Significant product innovations, technical advances or the intensification of price competition by competitors could adversely affect the Group's operating results. Some of these competitors may have greater financial, marketing and other resources than Smith & Nephew. These competitors may be able to initiate technological advances in the field, deliver products on more attractive terms, more aggressively market their products or invest larger amounts of capital and research and development lR&D) into their businesses. There is a possibility of further consolidation of competitors, which could adversely affect the Group's ability to compete with larger companies due to insufficient financial resources. If any of the Group's businesses were to lose market share or achieve lower than expected revenue growth, there could be a disproportionate adverse impact on the Group's share price and its strategic options. Competition exists among healthcare providers to gain patients on the basis of quality, service and price. There has been some consolidation in the Group's customer base and this trend is expected to continue. Some customers have joined group purchasing organisations or introduced other cost containment measures that could lead to downward pressure on prices or limit the number of suppliers in certain business areas, which could adversely affect Smith & Nephew's results of operations and hinder its growth potential.

Continual development and introduction of new products

The medical devices industry has a rapid rate of new product introduction. In order to remain competitive, the Group must continue to develop innovative products that satisfy customer needs and preferences or provide cost or other advantages. Developing new products is a costly, lengthy and uncertain process. The Group may fail to innovate due to low R&D investment, a R&D skills gap or poor product development. A potential product may not be brought to market or not succeed in the market for any number of reasons, including failure to work optimally, failure to receive regulatory approval, failure to be cost-competitive, infringement of patents or other intellectual property rights and changes in consumer demand. The Group's products and technologies are also subject to marketing attack by competitors. Furthermore, new products that are developed and marketed by the Group's competitors may affect price levels in the various markets in which the Group operates. If the Group's new products do not remain competitive with those of competitors, the Group's revenue could decline.

The Group maintains reserves for excess and obsolete inventory resulting from the potential inability to sell its products at prices in excess of current carrying costs. Marketplace changes resulting from the introduction of new products or surgical procedures may cause some of the Group's products to become obsolete. The Group makes estimates regarding the future recoverability of the costs of these products and records a provision for excess and obsolete inventories based on historical experience, expiration of sterilisation dates and expected future trends. If actual product life cycles, product demand or acceptance of new product introductions are less favourable than

projected by management, additional inventory write- downs may be required.

Dependence on government and other funding

In most markets throughout the world, expenditure on medical devices is ultimately controlled to a large extent by governments. Funds may be made available or withdrawn from healthcare budgets depending on government policy. The Group is therefore largely dependent on future governments providing increased funds commensurate with the increased demand arising from demographic trends.

Pricing of the Group's products is largely governed in most markets by governmental reimbursement authorities. Initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation, excise taxes and competitive pricing, are ongoing in markets where the Group has operations. This control may be exercised by determining prices for an individual product or for an entire procedure. The Group is exposed to government policies favouring locally sourced products. The Group is also exposed to changes in reimbursement policy, tax policy and pricing which may have an adverse impact on revenue and operating profit. Provisions in US healthcare legislation which previously imposed significant taxes on medical device manufacturers have been suspended since 2016 but may be reinstated. There may be an increased risk of adverse changes to government funding policies arising from deterioration in macro-economic conditions from time to time in the Group's markets.

The Group must adhere to the rules laid down by government agencies that fund or regulate healthcare, including extensive and complex rules in the US. Failure to do so could result in fines or loss of future funding.

World economic conditions

Demand for the Group's products is driven by demographic trends, including the ageing population and the incidence of osteoporosis and obesity. Supply of, use of and payment for the Group's products are also influenced by world economic conditions which could place increased pressure on demand and pricing, adversely impacting the Group's ability to deliver revenue and margin growth. The conditions could favour larger, better capitalised groups, with higher market shares and margins. As a consequence, the Group's prosperity is linked to general economic conditions and there is a risk of deterioration of the Group's performance and finances during adverse macro-economic conditions.

During 2018, economic conditions worldwide continued to create several challenges for the Group, including the US Administration's changed approach to trade policy, deferrals of procedures, heightened pricing pressure, significant declines in capital equipment expenditures at hospitals and increased uncertainty over the collectability of government debt, particularly those in the Emerging Markets. These factors tempered the overall growth of the Group's global markets and could have an increased impact on growth in the future.

Political uncertainties

The Group operates on a worldwide basis and has distribution channels, purchasing agents and buying entities in over 100 countries. Political upheaval in some of those countries or in surrounding regions may impact the Group's results of operations. 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 products or investments in that country. Furthermore, changes in government policy regarding preference for local suppliers, import quotas, taxation or other matters could adversely affect the Group's revenue and operating profit. War, economic sanctions, terrorist activities or other conflict could also adversely impact the Group. These risks may be greater in Emerging Markets, which account for an increasing portion of the Group's business.

There remain heightened levels of political and regulatory uncertainty in the UK following the result of the referendum in June 2016 to leave the European Union, the triggering of Article 50 in March 2017 and the general election in June 2017. As of the date of this report, there remains uncertainty as to the UK's future relationship with the EU. This may adversely impact trading performance across the sector. Regulatory uncertainty forms the most significant risk presently; the ability for us to continue to manufacture and register our products in a compliant manner for global distribution is key. Smith & Nephew has taken steps to prepare for the various Brexit scenarios, including moving certain of its product certifications from UK-based notified bodies to notified bodies based in the EU. The UK accounts for approximately 5% of global Group revenue and the majority of our manufacturing takes place outside the UK and EU. There is also uncertainty around US-China trade relations, which has resulted in tariffs on some medical devices being exported between the two countries

Currency fluctuations

Smith & Nephew's results of operations are affected by transactional exchange rate movements in that they are subject to exposures arising from revenue in a currency different from the related costs and expenses. The Group's manufacturing cost base is situated principally in the US, the UK, China, Costa Rica and Switzerland, from which finished products are exported to the Group's selling operations worldwide. Thus, the Group is exposed to fluctuations in exchange rates between the US Dollar, Sterling and Swiss Franc and the currency of the Group's selling operations, particularly the Euro, Australian Dollar and Japanese Yen. If the US Dollar, Sterling or Swiss Franc should strengthen against the Euro, Australian Dollar and the Japanese Yen, the Group's trading margin could be adversely affected. The Group manages the impact of exchange rate movements on revenue and cost of goods sold by a policy of transacting forward foreign currency commitments when firm purchase orders are placed. In addition, the Group's policy is for forecast transactions to be covered between 50% and 90% for up to one year. However, the Group is exposed to medium to long-term adverse movements in the strength of currencies compared to the US Dollar. The Group uses the US Dollar as its reporting currency. The US Dollar is the functional currency of Smith & Nephew plc. The Group's revenues, profits and earnings are also affected by exchange rate movements on the translation of results of operations in foreign subsidiaries for financial reporting purposes. See 'Liquidity and capital resources' on page 39.

Manufacturing and supply

The Group's manufacturing production is concentrated at main facilities in Memphis, Mansfield and Oklahoma City in the US, Hull and Warwick in the UK, Aarau in Switzerland, Tuttlingen in Germany, Devrukh in India, Suzhou and Beijing in China, Alajuela in Costa Rica, Puschino in Russia and Curacao, in Dutch Caribbean. If major physical disruption took place at any of these sites, it could adversely affect the results of operations. Physical loss and consequential loss insurance is carried to cover such risks but is subject to limits and deductibles and may not be sufficient to cover catastrophic loss. Management of orthopaedic inventory is complex, particularly forecasting and production planning. There is a risk that failures in operational execution could lead to excess inventory or individual product shortages.

The Group is reliant on certain key suppliers of raw materials, components, finished products and packaging materials or in some cases on a single supplier. These suppliers must provide the materials and perform the activities to the Group's standard of quality requirements. A supplier's failure to meet expected quality standards could create liability for the Group and adversely affect sales of the Group's related products. The Group may be forced to pay higher prices to obtain raw materials, which it may not be able to pass on to its customers in the form of increased prices for its finished products. In addition, some of the raw materials used may become unavailable, and there can be no assurance that the Group will be able to obtain suitable and cost effective substitutes. Any interruption of supply caused by these or other factors could negatively impact Smith & Nephew's revenue and operating profit.

The Group will, from time to time including as part of the APEX programme, outsource or insource the manufacture of components and finished products to third parties and will periodically relocate the manufacture of product and/or processes between existing and/or new facilities. While these are planned activities, with these transfers there is a risk

of disruption to supply.

Requirements of global regulatory agencies have become more stringent in recent years and we expect them to continue to do so. The Group's Quality and Regulatory Affairs team is leading a major Group-wide programme to prepare for implementation of the EU Medical Devices Regulation lMDR), which came into force in May 2017, with a three-year transition period until May 2020. The regulation includes new requirements for the manufacture, supply and sale of all CE marked products sold in Europe and requires the reregistration of all medical devices, regardless of where they are manufactured.

Attracting and retaining key personnel

The Group's continued development depends on its ability to hire and retain highly-skilled personnel with particular expertise. This is critical, particularly in general management, research, new product development and in the sales forces. If Smith & Nephew is unable to retain key personnel in general management, research and new product development or if its largest sales forces suffer disruption or upheaval, its revenue and operating profit would be adversely affected. Additionally, if the Group is unable to recruit, hire, develop and retain a talented, competitive workforce, it may not be able to meet its strategic business objectives.

Proprietary rights and patents

Due to the technological nature of medical devices and the Group's emphasis on serving its customers with innovative products, the Group has been subject to patent infringement claims and is subject to the potential for additional claims. Claims asserted by third parties regarding infringement of their intellectual property rights, if successful, could require the Group to expend time and significant resources to pay damages, develop non-infringing products or obtain licences to the products which are the subject of such litigation, thereby affecting the Group's growth and profitability. Smith & Nephew attempts to protect its intellectual property and regularly opposes third party patents and trademarks where appropriate in those areas that might conflict with the Group's business interests. If Smith & Nephew fails to protect and enforce its intellectual property rights successfully, its competitive position could suffer, which could harm its results of operations.

Product liability claims and loss of reputation

The development, manufacture and sale of medical devices entail risk of product liability claims or recalls. Design and manufacturing defects with respect to products sold by the Group or by companies it has acquired could damage, or impair the repair of, body functions. The Group may become subject to liability, which could be substantial, because of actual or alleged defects in its products. In addition, product defects could lead to the need to recall from the market existing products, which may be costly and harmful to the Group's reputation. There can be no assurance that customers, particularly in the US, the Group's largest geographical market, will not bring product liability or related claims that would have a material adverse effect on the Group's financial position or results of operations in the future, or that the Group will be able to resolve such claims within insurance limits. As at 31 December 2018, a provision of $192m is recognised relating to the present value of the estimated costs to resolve all unsettled known and unknown anticipated metal-on-metal hip implant claims globally.

Regulatory standards and compliance in the healthcare industry

Business practices in the healthcare industry are subject to regulation and review by various government authorities. In general, the trend in many countries in which the Group does business is towards higher expectations and increased enforcement activity by governmental authorities. While the Group is committed to doing business with integrity and welcomes the trend to higher standards in the healthcare industry, the Group and other companies in the industry have been subject to investigations and other enforcement activity that have incurred and may continue to incur significant expense. Under certain circumstances, if the Group were found to have violated the law, its ability to sell its products

to certain customers could be restricted.

International regulation

The Group operates across the world and is subject to extensive legislation, including anti-bribery and corruption and data protection, in each country in which the Group operates. Our international operations are governed by the UK Bribery Act and the US Foreign Corrupt Practices Act which prohibit us or our representatives from making or offering improper payments to government officials and other persons or accepting payments for the purpose of obtaining or maintaining business. Our international operations in the Emerging Markets which operate through distributors increase our Group exposure to these risks.

The Group is also required to comply with the requirements of the EU General Data Protection Regulation (GDPR), which imposes additional obligations on companies regarding the handling of personal data and provides certain individual privacy rights to persons whose data is stored and became effective on 25 May 2018. As privacy and data protection have become more sensitive issues for regulators and consumers, new privacy and data protection laws, such as the GDPR, continue to develop in ways we cannot predict. Ensuring compliance with evolving privacy and data protection laws and regulations on a global basis may require us to change or develop our current business models and practices and may increase our cost of doing business. Despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities as enforcement of such legislation has increased in recent years on companies and individuals where breaches are found to have occurred. Failure to comply with the requirements of privacy and data protection laws, including GDPR, could adversely affect our business, financial condition or results of operations.

Regulatory approval

The international 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.

National regulatory authorities administer and enforce a complex series of laws and regulations that govern the design, development, approval, manufacture, labelling, marketing and sale of healthcare products. They also review data supporting the safety and efficacy of such products. Of particular importance is the requirement in many countries that products be authorised or registered prior to manufacture, marketing or sale and that such authorisation or registration be subsequently maintained. The major regulatory agencies for Smith & Nephew's products include the Food and Drug Administration lFDA) in the US, the Medicines and Healthcare products Regulatory Agency in the UK, the Ministry of Health, Labour and Welfare in Japan, the China Food and Drug Administration and the Australian Therapeutic Goods Administration. At any time, the Group is awaiting a number of regulatory approvals which, if not received, could adversely affect results of operations. In 2017, the EU reached agreement on a new set of Medical Device Regulations which entered into force on 25 May 2017. These have a three-year transition period and therefore, will fully apply in EU Member States from 26 May 2020.

The trend is towards more stringent regulation and higher standards of technical appraisal. Such controls have become increasingly demanding to comply with and management believes that this trend will continue. Regulatory requirements may also entail inspections for compliance with appropriate standards, including those relating to Quality Management Systems or Good Manufacturing Practices regulations. All manufacturing and other significant facilities within the Group are subject to regular internal and external audit for compliance with national medical device regulation and Group policies. Payment for medical devices may be governed by reimbursement tariff agencies in a number of countries. Reimbursement rates may be set in response to perceived economic value of the devices, based on clinical and other data relating to cost, patient outcomes and comparative effectiveness. They may also be affected by overall government budgetary considerations. The Group believes that its emphasis on innovative products and services should contribute to success in this environment. Failure to comply with these regulatory requirements

could have a number of adverse consequences, including withdrawal of approval to sell a product in a country, temporary closure of a manufacturing facility, fines and potential damage to Company reputation.

Failure to make successful acquisitions

A key element of the Group's strategy for continued growth is to make acquisitions or alliances to complement its existing business. Failure to identify appropriate acquisition targets or failure to conduct adequate due diligence or to integrate them successfully would have an adverse impact on the Group's competitive position and profitability. This could result from the diversion of management resources towards the acquisition or integration process, challenges of integrating organisations of different geographic, cultural and ethical backgrounds, as well as the prospect of taking on unexpected or unknown liabilities. In addition, the availability of global capital may make financing less attainable or more expensive and could result in the Group failing in its strategic aim of growth by acquisition or alliance.

Relationships with healthcare professionals

The Group seeks to maintain effective and ethical working relationships with physicians and medical personnel who assist in the research and development of new products or improvements to our existing product range or in product training and medical education. If we are unable to maintain these relationships our ability to meet the demands of our customers could be diminished and our revenue and profit could be materially adversely affected.

Reliance on sophisticated information technology

The Group uses a wide variety of information systems, programmes and technology to manage our business. The Group also develops and sells certain products that are or will be connected to networks and/or the internet. Our systems are vulnerable to a cyber attack, malicious intrusion, loss of data privacy or any other significant disruption. Our systems have been and will continue to be the target of such threats. We have systems in place to minimise the risk and disruption of these intrusions and to monitor our systems on an ongoing basis for current or potential threats. There can be no assurance that these measures will prove effective in protecting Smith & Nephew from future interruptions and as a result the performance of the Group could be materially adversely affected.

Other risk factors

Smith & Nephew is subject to a number of other risks, which are common to most global medical technology groups and are reviewed as part of the Group's Risk Management process.

Appendix B - Directors' Responsibility Statement pursuant to Disclosure and Transparency Rule 4

The following statement is extracted from page 116 of the 2018 Annual Report and is repeated here for the purposes of compliance with DTR 6.3.5. This statement relates solely to the 2018 Annual Report and is not connected to the extracted information set out in this announcement or the Press Release.

The Directors confirm that, to the best of each person's knowledge:

- the financial statements, prepared in accordance with the applicable set of accounting standards, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole; and

- the Strategic Report and Directors' Report include a fair review of the development and performance of the business and the position of the issuer and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

Appendix C - Related Party Transactions

Except for transactions with associates (see Note 23.2 to the 2018 Annual Report on page 177), no other related party had material transactions or loans with Smith & Nephew over the last three financial years.

Susan Swabey
Company Secretary
Smith & Nephew plc

Tel: 01923 477317

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: March 04, 2019

By: /s/ Susan Swabey

Susan Swabey
Company Secretary