Understanding Our Key Risks

Dechra is one of only a handful of listed veterinary pharmaceuticals companies in the FTSE. We therefore believe it is important to summarise the key distinctions between the animal and human pharmaceutical industries in order to provide a better understanding of our risk profile.

The business of developing and marketing animal pharmaceuticals shares a number of characteristics with human pharmaceutical businesses. These similarities include the need to conduct clinical trials to prove product safety and efficacy, obtain regulatory approval for new products, complex and highly regulated product manufacturing, and to market products based on approved clinical claims. However, there are also significant differences between animal and human pharmaceutical businesses, including:

- **Product development is generally faster, cheaper and more predictable and sustainable:** Development of animal medicines typically requires fewer clinical studies with fewer subjects and is conducted directly in the target species. Decisions on product safety, efficacy and likelihood of success can therefore be made more quickly.
- **Diversified product portfolios:** Animal pharmaceuticals businesses are generally less reliant on a small number of 'blockbuster' products. Animal health products are sold across different regions which may have distinct product requirements. As a result, animal health products often have a smaller market size and the performance of any single product typically has less impact on overall business performance.
- **Stronger customer relationships and brand loyalty:** Companion Animal Products are directly prescribed and often dispensed and sold by veterinarians which contributes to building brand loyalty, which continues after the loss of patent protection or regulatory exclusivity.
- **Lower pricing pressure:** Livestock producers and pet owners generally pay for animal healthcare themselves. Pricing decisions are not influenced by government payors that are involved in product and pricing decisions for human medicines.
- **Less price erosion by generic competition:** Generic competition in animal healthcare, whilst playing an important role, has a lower impact on prices compared to human pharmaceuticals because of the smaller average market size of each product opportunity, stronger customer relationships and brand loyalty.

The SET has identified and agreed key risks with the Board. Of these, a number are deemed to be generic risks facing every business including failure to comply with financial reporting regulation, foreign exchange, IT systems failure and non-compliance with legislation. The table below therefore details the ten principal risks that are specific to our business and provides information on:

- how they link to Group strategy;
- their potential impact on the business; and
- what controls are in place to mitigate them.

Link to Strategic Growth Driver and Enabler	Risk	Potential Impact	Control and Mitigating Actions	Trends
	Competitor Risk: Competitor products launched against one of our leading brands (e.g. generics or a superior product profile). We depend on data exclusivity periods or patents to have exclusive marketing rights for some of our products. Although we maintain a broad portfolio of products, our unique products like *Vetoryl* and *Felimazole* have built a market which may be attractive to competitors.	Revenues and margins may be adversely affected should competitors launch a novel or generic product that competes with one of our unique products upon the expiry or early loss of patents. Costs may increase due to defensive marketing activity.	We focus on lifecycle management strategies for our key products to ensure they fulfil evolving customer requirements. Product patents are monitored and defensive strategies are developed towards the end of the patent life or the data exclusivity period. We monitor market activity prior to competitor products being launched, and develop a marketing response strategy to mitigate competitor impact.	▲ Competitor product launches against some of our key products

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	**Market Risk:** The emergence of veterinary buying groups and corporate customers. We sell and promote primarily to veterinary practices and distribute our products through wholesaler and distributor networks in most markets. In a number of mature markets, veterinarians are establishing buying groups to consolidate their purchasing, and corporate customers are also emerging.	The emergence of corporate customers and buying groups represents an opportunity to increase sales volumes and revenue but may result in reduced margins. Our reputation and relationships with veterinary practices could also be adversely affected.	We manage and monitor our national and European pricing policies to ensure equitable pricing for each customer group. Our relationships with larger customers are managed by key account managers. Our marketing strategy is designed to support veterinarians in retaining customers by promoting the benefits of our product portfolio in our major therapeutic areas.	
	**Acquisition Risk:** Identification of acquisition candidates and their potential integration. Identification of suitable candidates and securing a successful approach involves a high degree of uncertainty. Acquired products or businesses may fail to deliver expected returns due to over-valuation or integration challenges.	Failure to identify or secure suitable targets could slow the pace at which we can expand into new markets or grow our portfolio. Acquisitions could deliver lower profits than expected or result in intangible assets impairment.	We have defined criteria for screening acquisition targets and we conduct commercial, clinical, financial and legal due diligence. The Board reviews acquisition plans and progress regularly and approves all potential transactions. The SET manages post-acquisition integration and monitors the delivery of benefits and returns.	 Successful integration of recent acquisitions
	**Product Development Risk:** Failure to deliver major products either due to pipeline delays or newly launched products not meeting revenue expectations. The development of pharmaceutical products is a complex, risky and lengthy process involving significant financial, R&D and other resources. Products that initially appear promising may be delayed or fail to meet expected clinical or commercial expectations or face delays in regulatory approval. It can also be difficult to predict whether newly launched products will meet commercial expectations.	A succession of clinical trial failures could adversely affect our ability to deliver shareholder expectations and could also damage our reputation and relationship with veterinarians. Our market position in key therapeutic areas could be affected, resulting in reduced revenues and profits. Where we are unable to recoup the costs incurred in developing and launching a product this would result in impairment of intangible assets.	Potential new development candidates are assessed from a commercial, financial and scientific perspective by a multi-functional team to allow senior management to make decisions on which ones to progress. The pipeline is discussed regularly by senior management, including the Chief Executive Officer and Chief Financial Officer. Regular updates are also provided to the Board. Each development project is managed by co-project leaders who chair project team meetings. Before costly pivotal studies are initiated, smaller proof of concept pilot studies are conducted to assess the effects of the drug on target species and for the target indication. In respect of all new product launches a detailed marketing plan is established and progress against that plan is regularly monitored. The Group ensures that it has a detailed market knowledge and retains close contact with customers through its management and sales teams which are trained to a high standard.	

Understanding Our Key Risks
continued

Link to Strategic Growth Driver and Enabler	Risk	Potential Impact	Control and Mitigating Actions	Trends
	Regulatory Risk: Failure to meet regulatory requirements. We conduct our business in a highly regulated environment, which is designed to ensure the safety, efficacy, quality, and ethical promotion of pharmaceutical products. Failure to adhere to regulatory standards or to implement changes in those standards could affect our ability to register, manufacture or promote our products.	Delays in regulatory reviews and approvals could impact the timing of a product launch and have a material effect on sales and margins. Any changes made to the manufacturing, distribution, marketing and safety surveillance processes of our products may require additional regulatory approvals, resulting in additional costs and/or delays. Non-compliance with regulatory requirements may result in delays to production or lost sales.	The Group strives to exceed regulatory requirements and ensure that its employees have detailed experience and knowledge of the regulations. Manufacturing and Regulatory have established quality systems and standard operating procedures in place. Regular contact is maintained with all relevant regulatory bodies in order to build and strengthen relationships and facilitate good communication lines. The regulatory and legal teams keep updated in respect of changes with a view to ensuring that the business is equipped to deal with, and adhere to, such changes. Where changes are identified which could affect our ability to market and sell any of our products, a response team is created in order to mitigate the risk. External consultants are used to audit our manufacturing quality systems.	
	Regulatory Risk: Continuing pressure on reducing antibiotic use. The issue of the potential transfer of antibacterial resistance from food producing animals to humans is subject to regulatory discussions. In some countries this has led to government recommendations on reducing the use of antibiotics in food producing animals.	Reduction in sales of our antimicrobial product range. Our reputation could be adversely impacted if we do not respond appropriately to government recommendations.	Regular contact is maintained with relevant veterinary authorities to ensure that we have a comprehensive understanding of regulatory changes. We strive to develop new products and minimise antimicrobial resistance concerns.	Antibiotic decline has increased in the UK and Denmark
	Reliance on Third Parties Risk: A supply failure on a key product may affect our ability to develop, make, or sell our products. We rely on third parties for the supply of all raw materials for products that we manufacture in-house. We also purchase many of our finished products from third party manufacturers.	Raw material supply failures may cause: • Increased product costs due to difficulties in obtaining scarce materials on commercially acceptable terms; • product shortages due to manufacturing delays; or • delays in clinical trials due to shortage of trial products. Shortages in manufactured products and third party supply failures on finished products may result in lost sales.	We monitor the performance of our key suppliers and act promptly to source from alternative suppliers where potential issues are identified. The top ten Group products are regularly reviewed in order to identify the key suppliers of materials or finished products. We maintain buffer stocks and dual sourcing arrangements of key products. All contracts with suppliers are reviewed from both a commercial and legal perspective to try to ensure that assignment of the contract is allowed should there be a change of control of either of the contracting parties. We have recruited a dedicated CMO Director to manage our third party supplier network.	

Link to Strategic Growth Driver and Enabler	Risk	Potential Impact	Control and Mitigating Actions	Trends
	**Reliance on Third Parties Risk:** Loss of key third party manufacturing customers from DPM. Other sales, relating to third party manufacturing and other non-core activities, represents approximately 9.2% of Group revenues.	Loss of a key customer can impact manufacturing revenues and lead to an increase in the cost of goods of the remaining portfolio.	The DPM sales team maintains relationships with key customers. Robust supply agreements are in place with each of our key customers and are regularly reviewed. Monthly customer service level monitoring and reporting is in place.	 Strategy to reduce third party manufacturing contracts
	**People Risk:** Failure to retain high calibre, talented senior managers and other key roles in the business. Our growth plans and future success are dependent on retaining knowledgeable and experienced senior managers and key staff.	Loss of key skills and experience could erode our competitive advantage and could have an adverse impact on results. Inability to attract and retain key personnel may weaken succession planning.	The Nomination Committee oversees succession planning for the Board and the SET. Succession plans are in place for the SET together with development plans for key senior managers. Key person insurance is in place where appropriate. Remuneration packages are reviewed on an annual basis in order to help ensure that the Group can continue to retain, incentivise and motivate its employees.	 Board and SET succession planning managed successfully
	**People Risk:** Failure to resource the business to achieve our strategic ambitions, particularly on geographical expansion and acquisition. As Dechra expands into new markets and acquires new businesses or science we recognise that we may need new people with different skills, experience and cultural knowledge to execute our strategy successfully in those markets and business areas.	Failure to recruit or develop good quality people could result in: • capability gaps in new markets; • challenges in integrating new acquisitions; or • overstretched resources. This could delay implementation of our strategy and we may not meet shareholders' expectations.	The Group HR Director reviews the organisational structure with the SET twice a year to aim to ensure that the organisation is fit for purpose and to assess the resourcing implications of planned changes or strategic imperatives. A development programme is in place to identify opportunities to recruit new talent and develop existing potential.	 Successful recruitment of DPM management team

Key to Strategic Growth Drivers:

 Pipeline Delivery

 Portfolio Focus

 Geographical Expansion

 Acquisition

Key to Strategic Enablers:

 Manufacturing and Supply Chain

 Technology

 People

Key to Risk Trend:

 Increased risk

 Decreased risk

 No change

Read **Delivering Our Strategy** on pages 13 to 15