X234/701

NATIONAL QUALIFICATIONS 2011

WEDNESDAY, 25 MAY
1.00 PM – 3.45 PM

BUSINESS MANAGEMENT
ADVANCED HIGHER

100 marks are allocated to this paper.

Candidates should spend 15 minutes reading the case study material and the questions.

Answer **all** questions in Section One (50 marks).

Answer **two** questions in Section Two (50 marks).

Note: The questions are printed on a separate sheet inserted inside the front cover of this paper.

LI X234/701 6/1010

PROSTRAKAN plc

Background Information

ProStrakan plc is an international pharmaceutical company. It was established in 2004 after a merger between Strakan, a Scottish based company formed in 1995, and a French company, ProSkelia. ProStrakan became a public limited company in 2005. Its headquarters is in Galashiels in the Scottish Borders and it has development facilities there and in New Jersey, USA. Its products are prescription medicines and its core markets are the European Union (primarily the UK but also Germany, France, Spain and Sweden) and the United States. It employs around 300 people worldwide, about 90 of whom are in Scotland.

ProStrakan's Business Model

ProStrakan's business is branded medical products. It concentrates on speciality products which treat a very specific medical condition and which meet a gap in existing provision. ProStrakan could be described as a specialist company which aims at niche markets in developed economies.

Most of its activities involve licensing. It obtains licences from other companies (in-licensing) to develop and/or market products that they have devised. It also grants licences to other companies (out-licensing) to develop and/or market products which it owns.

This specialist approach means that ProStrakan can avoid some, but not all, of the costs and the risks of developing new drug products. However, it also means that ProStrakan depends heavily on the scientific and marketing skills and experience of its staff as well as their ability to identify and exploit emerging new opportunities. This requires knowledge and expertise relating to developments in the pharmaceutical industry and market circumstances in different countries.

Exhibit 1 gives some further information on ProStrakan's processes.

Exhibit 2 gives some examples of the company's products.

Growth and Development of ProStrakan

Growth is a key objective of ProStrakan because growth will enable it to increase its revenue. It can then re-invest this revenue in the development and marketing of new products. In addition, increased revenue will enable it to become profitable.

ProStrakan has grown organically and through merger and acquisition. It also often enters into collaborative arrangements with other companies as part of its in-licensing and out-licensing deals. Three examples are discussed on *Page three*.

Example 1 – Merger between Strakan and ProSkelia [2004]

ProSkelia, based in Paris, was formed when part of Aventis, a big French pharmaceutical company, set up its bone diseases research division as a separate company. ProSkelia merged on a 50-50 basis with the Galashiels based Strakan to form a new company ProStrakan. ProSkelia became the Drug Discovery Unit of ProStrakan and retained its name, now being known as ProSkelia SASU.

The merger brought together complementary activities in the pharmaceutical industry – research from ProSkelia and in-licensing and commercial development from Strakan. ProStrakan now had a mixed research/development and in-licensing business model which it used to obtain new products through its own discovery of new drugs and by licensing ideas from others.

Example 2 – Sale of ProSkelia SASU [2005]

In 2005, ProStrakan sold its Drug Discovery Unit, ProSkelia SASU, to Galapagos NV, a Dutch pharmaceutical company, for 12·5m worth of euros in Galapagos shares and cash payments of 14·5m euros spread over a period of time. This marked a significant change of strategy for ProStrakan. It now concentrated on the later stages of drug development such as clinical trials and bringing new drugs to market. It would no longer be involved in research to develop new drugs from scratch.

A major reason for the de-merger was that ProStrakan could grow more quickly without ProSkelia SASU. It had transpired that new commercial products based on the research undertaken by ProSkelia would take longer to come to fruition than had been anticipated. In addition, the success of other products which ProStrakan was developing was greater than expected. De-merging meant that money previously needed to fund research could now be used to further develop and market these successful products, as well as for any new in-licensing deals. This could reduce uncertainty about the future, make more cash available, lead to increased revenue and enable ProStrakan to reach break-even point more quickly.

Exhibit 3 gives some more background to the merger and to the subsequent de-merger outlined above.

Example 3 – Expansion in the USA

In 2007, ProStrakan set up a development facility and sales office in New Jersey, USA. A key reason was that approval was expected to sell Sancuso, ProStrakan's successful cancer patch, in the USA. Approval to sell Sancuso in the USA was granted in 2008. ProStrakan now has a presence in the world's 2 biggest pharmaceutical markets: Europe and the USA. It is estimated that 1·4m people are diagnosed with cancer in the US each year.

As part of its expansion, ProStrakan was able to agree a 3 year deal in 2007 with NovaQuest, a US company which specialises in partnerships with smaller biotech and speciality pharmaceutical companies. Novaquest will invest $45m to enable ProStrakan to recruit a US sales force for Sancuso. NovaQuest will also invest up to a further $10m to launch and market Sancuso in America. In return, NovaQuest will get royalty payments plus a 10 year right to buy shares in ProStrakan for a fixed price of 75·5p.

[Turn over

Other Collaborative Arrangements

ProStrakan has made a number of agreements with other companies to sell Sancuso in ProStrakan's non-core markets. These out-licensing deals allow ProStrakan to tap into the specialist expertise of others in the same way as in-licensing allows it to capitalise on its own specialist capabilities.

For example, in 2008, it made an agreement with JapanBridge to develop and market Sancuso in Japan, China and some other parts of Asia. This was JapanBridge's first exclusive licence from a Western pharmaceutical company and it will earn ProStrakan US$26m in upfront and milestone payments.

Employee Relations

ProStrakan is based in Galashiels because Harry Stratford, one of the founders of Strakan, was a keen salmon fisherman. He enjoyed fishing in the Borders and thought other people would be attracted to the area because of the lack of congestion and the beauty of the countryside. The company has not encountered any difficulties in attracting the skilled professional personnel on which it depends.

Its corporate social responsibility policy includes ensuring that the creative talents, commitment and energy that every employee brings to ProStrakan are fully valued and respected. In addition, the specialist and professional nature of the work that employees do means that they can see how their input affects the business. Being able to see the result of what they have done leads to pride in the work they do. ProStrakan involves employees in its objectives by communicating in several different ways, including holding regular meetings.

Financial Situation

Up until the financial year ending in 2009, ProStrakan had been able to make a gross profit by covering the costs of sales. However, it had not been able to cover all its expenses and had not, therefore, been able to declare an overall profit. It had not paid dividends to shareholders. Break-even is predicted to occur in the very near future.

ProStrakan needs finance to continue developing and marketing its products. Its successes in product sales and licensing deals have been crucial in helping it to earn revenue which it can re-invest. In 2007, it arranged a secured debt facility from a financial institution. ProStrakan can draw on this facility when required to borrow up to a maximum of £50m. Its success in building sales means that, unlike some other Scottish based drug companies, it has not encountered difficulties in obtaining cash.

Exhibit 4 gives information on ProStrakan's performance.

[The above information is taken from ProStrakan plc Annual Reports 2005–2009. Additional information came from the company website at www.ProStrakan.co.uk.]

NB Unless stated otherwise, the above, and the accompanying exhibits, are current at 1 September 2009 and refer to the situation at that date.

Exhibit 1 – ProStrakan's Main Processes

ProStrakan's aim is to "*alleviate the often distressing symptoms associated with hitherto poorly treated conditions. We will achieve this by introducing novel and effective prescription medicines to the market, in the process creating a significant international pharmaceutical business.*"

It has teams of experts who work in 4 main processes involved in discovering a new drug product and taking it to market. The extent of ProStrakan's involvement depends on the product concerned – it may be involved in only one of the areas for example. The 4 processes are:

Acquire – Finding products and partners

The business development team searches for products developed by other firms which fit with ProStrakan's portfolio of products and which ProStrakan can license (in-licensing). ProStrakan also grants licences to other companies (out-licensing) to take forward products developed by ProStrakan which are not core to its business.

Develop – Developing new products

Once potential new products have been discovered, they have to undergo considerable development to make sure that they are safe, that they do work on patients and that possible side-effects have been identified and understood. For new drugs, this means taking them through clinical trials. ProStrakan can guide products (usually licensed from others) through clinical trials, although it often works with products which have passed some or all the stages of clinical trials.

Approvals – Gaining approval from regulators

Before new drug products can be marketed they must be approved by regulators responsible for the country or geographical area where they are to be sold. Each regulatory body has its own procedures and standards. ProStrakan has technical experts who can manage the process of taking new products through regulatory approval in its core markets. These regulations can mean that a product can be sold in one country but not in another – for example when approval has been granted in one country but is pending in another.

Market – Taking products to market

Once approval has been achieved, the new product must be marketed. ProStrakan has sales and marketing specialists who can devise and implement campaigns to make doctors and others aware of the new product so that it can be prescribed to patients. The marketing of drugs is also often governed by strict regulations which vary from country to country.

NB Developing new drug products can be very risky and costly. Clinical trials, for example, may show that new products do not alleviate a patient's condition. In other cases, regulators may not grant approval, or marketing campaigns may not persuade doctors to prescribe a new drug which has been approved. One of the reasons that ProStrakan concentrates on the later stages of development and marketing is that this can help to reduce the risks of new products. It also reduces risks by concentrating on new ways to use existing drugs which have been proven to work.

[Turn over

Exhibit 2 – Examples of ProStrakan's Products

The table below gives some examples of ProStrakan's products. All are branded prescription drugs, ie they are only available on prescription from a medical practitioner.

Name of product	***Description of product***	***Other information***
Sancuso	A skin patch for cancer patients which provides a well-established drug, granisetron, to prevent nausea associated with chemotherapy and avoids the need for injections or pills.	Developed by ProStrakan itself and for which ProStrakan owns the global rights. Marketed by ProStrakan in the UK, and from 2009 in the USA. Also out-licensed in 72 countries.
Abstral (previously known as Rapinyl)	A fast-dissolving tablet which administers a well recognised drug, fentanyl, to cancer patients suffering from what is known as breakthrough pain which can occur during cancer treatment.	ProStrakan in-licensed the European rights from the Swedish company, Orexo, in 2007 and the rights for North America in 2008. Launched in Sweden in 2008 and expected to be sold in the USA from 2010.
Adcal D3	Designed to treat a deficiency in calcium and vitamin D in patients suffering from osteoporosis. It is an oral supplement available in both a chewable and soluble form. Again it is based on existing established treatments.	Available in the UK only, this is an example of a country specific product. Over 300,000 people in the UK suffer from osteoporosis.
Xomolix (also known as Droperidol)	Used primarily in hospitals, it is an injectable drug to relieve post-operative nausea, again based on known treatments.	Originally sold in France it is now licensed in a further 8 European countries, including Germany. It is an example of a pan-European product.

Exhibit 3 – Merger and De-merger of ProSkelia

Merger of Strakan and ProSkelia to form ProStrakan

An important aspect of the merger was that it created a fully integrated pharmaceutical company which could undertake all stages of drug development from primary research to marketing the final product.

From Strakan's point of view, it offered an opportunity to expand into Europe. The merger also enabled ProStrakan to become big enough to have the foundation that it would need to grow in the future. As far as ProSkelia was concerned, the merger gave it direct access to development and marketing expertise which would help to turn research ideas into new products and bring these products to market.

The 2 companies fitted well together. Strakan was a specialty company specialising in later stage development and commercial activities, while ProSkelia focused on fundamental research and development. They had complementary management teams reflecting discovery and commercialisation and complementary technical expertise. ProSkelia's expertise in skeletal biology and steroid chemistry fitted well with Strakan's expertise in women's health and the health of older men.

Strakan and ProSkelia merged on 50-50 basis and this is why the name was changed. As part of the deal, Aventis took 12·7% of ProStrakan shares.

De-merger in 2005 with the sale of ProSkelia SASU to Galapagos NV

As part of the deal with Galapagos NV, ProStrakan retained some ongoing R & D partnerships with other drugs companies but, as part of the de-merger, Galapagos would get 25% of any royalties from these collaborations. ProStrakan also granted a licence to Galapagos for another programme which Galapagos will take through Phase II trials.

There were some possible costs for ProStrakan. One was a tax liability in France. When ProStrakan bought ProSkelia from Aventis, a condition of the sale was that ProStrakan would not sell shares in ProSkelia, as French law meant that Aventis would have to pay tax if shares were sold. When ProStrakan did sell the shares, Aventis became liable for the tax. In 2009, ProStrakan paid 9·15m euros to cover the tax due. ProStrakan could also lose out on benefits from new products which might result from further research by ProSkelia. It would no longer have a base in continental Europe and would be based solely in the UK.

[Turn over

Exhibit 4 – Performance of ProStrakan

Some financial and other data:

	2008	2007	2006	2005
Revenue (£m)	56·1	45·6	38·5	31·5
Gross profit (£m)	36·1	31·7	23·0	16·6
Loss (£m)	(25·1)	(17·3)	(29·6)	(33·8)
Cash Outflow (£m)	(9·5)	(14·7)	(18·6)	(27·8)
Growth in product sales (%)	+32	+22	+23	+46

Revenue from different geographical areas (£m)

	2008	2007	2006	2005
United Kingdom	27·5	23·8	20·7	15·5
EU (excluding UK)	26·2	17·1	15·0	15·6
United States	0·3	–	–	–
Other countries	2·1	4·7	2·8	0·3
Total	56·1	45·6	38·5	31·5

NB Figures for 2005 have a rounding up error.

Data from 2008–2009

- In the first part of 2009, sales of Sancuso in the US built up to 850 patches per week; 82 sales personnel were recruited in the USA instead of the 75 originally thought necessary.
- Agreements were reached with Invida Pharmaceuticals in Singapore for exclusive supply of Sancuso in parts of Pacific region, and with NewBridge in Dubai for rights in Turkey [NewBridge already has rights to Middle East and Africa].

Data from 2007–2008

- Sales revenue from pan-European products (ie ones sold in several countries across Europe and not just in one country) rose by 69%.
- ProStrakan agreed a joint venture with a Swedish company, Orexo. ProStrakan will sell 50% of its Swedish affiliate to Orexo and will collaborate with it in marketing and distributing both companies' products in Scandinavia.

[*END OF CASE STUDY*]

Marks

QUESTIONS

You should spend 15 minutes reading through the case study material on ProStrakan plc and the questions.

SECTION ONE

Answer ALL questions.

1. (*a*) Discuss the reasons why ProStrakan decided to expand in the USA in 2007. **6**

(*b*) Apart from expansion in the American market, analyse other actions ProStrakan has taken which can help it achieve the growth it is seeking. **6**

2. ProStrakan prides itself on the commitment shown by its workforce. Assess the factors that help to motivate its employees in Scotland. **6**

3. Despite not making a profit, ProStrakan has been successful. Analyse examples from the case study to show how its success in recent years could be measured. **6**

4. ProStrakan is a new and relatively small company which specialises in bringing new pharmaceutical products to market. Using examples from the case study, explain the benefits to ProStrakan of this specialisation. **8**

5. Discuss the importance to ProStrakan of deals with other companies. **4**

6. Explain the reasons Strakan and ProSkelia decided to merge to become ProStrakan in 2004. **4**

7. Analyse ProStrakan's decision to sell ProSkelia to NV Galapagos in 2005. (Your answer must include a force field diagram.) **10**

(50)

[Turn over for SECTION TWO

Marks

SECTION TWO

Answer any TWO of the following questions.

You may illustrate your answers in this section with examples from any companies or other organisations with which you are familiar.

8. (*a*) Examine how the use of different types of information technology can increase competitiveness of UK firms in the global market. **13**

(*b*) Describe the main ideas of the Human Relations School and discuss its relevance to modern day management. **12**

(25)

9. (*a*) Describe time and task management techniques and explain how they can be used to make a manager more effective. **13**

(*b*) Explain the stages of group development and assess how this process can influence the success of teams in businesses. **12**

(25)

10. (*a*) Assess the extent of the influence that stakeholders can have in affecting a multinational corporation's operations. **13**

(*b*) Describe each of the following and discuss how each one might affect a UK firm's profitability.

- Single European Market
- European Monetary Union **12**

(25)

11. (*a*) Describe the stages of change and discuss the benefits to an organisation of a properly managed change programme. **12**

(*b*) Evaluate the methods the UK Government can use to aid business during a recession. **13**

(25)

[*END OF QUESTIONS*]

ACKNOWLEDGEMENTS

Case Study—Information is taken from ProStrakan plc Annual Reports 2005–2009. Additional information came from the company website at **www.ProStrakan.com**. Reproduced by kind permission of ProStrakan Group plc.