

# Press Release

## ProStrakan Group plc

### Preliminary Results for the Year Ended 31 December 2010

**Galashiels, UK, 17 March 2011:** ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces its Preliminary Results for the year ended 31 December 2010.

#### FINANCIAL HIGHLIGHTS

- Total revenues of £100.2m (2009: £79.0m)
  - Continued strong European performance
  - Partnering income of £13.4m including £8.1m milestone payment on US approval of Fortesta (2009: £5.2m)
- EBITDA of £10.8m (2009: £5.1m loss)
- Operating profit of £6.1m (2009: £9.6m loss)
- Pre-tax loss reduced to £0.6m (2009: £15.0m)
- Closing cash position of £19.4m (31 December 2009: £19.0m)

#### OPERATING HIGHLIGHTS

- Continued European growth
  - European revenues up 21% to £80.0m
  - Abstral a key driver of growth
  - Adcal-D3 sales up 14% to £23.2m
- US business experienced challenges and successes
  - Sancuso sales of £6.8m despite manufacturing interruption
  - Fortesta approved by FDA
  - Abstral approved by FDA in early January 2011
- Worldwide partnering programme made a significant contribution
  - Partnering product sales revenues of £2.4m
  - Fortesta FDA approval triggered £8.1m (\$12.5m) milestone payment (cash received January 2011)
  - 13 approvals and 5 new product country launches through partners
- Refinancing of the Group's borrowing facility in January 2011
  - New strategic relationship with Paladin Labs Inc. announced

- Reduced rate of borrowing and capital repayments extended until January 2014
- Exclusive out-license distribution agreement for Canada and certain emerging territories

Commenting on the results, Peter Allen, Chairman & Acting Chief Executive of ProStrakan, said:

“From a low point in the middle of 2010, when events had become very challenging for ProStrakan, I am delighted to be in a position to report that, as a result of a great deal of hard work on the part of our many talented people, we were able to finish the year very strongly.

“Since then, we have received, from Kyowa Hakko Kirin, an offer to acquire ProStrakan which attaches full value to the business and is being recommended for shareholder acceptance by the Board, as well as having the support of the majority of our principal shareholders. This process is ongoing and, assuming it is approved by shareholders, ProStrakan’s acquisition by KHK will mark a new chapter in the ProStrakan story which, I believe, will be beneficial to all concerned – shareholders and staff alike.”

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**CHAIRMAN'S STATEMENT**

2010 was a year of challenges and opportunities for ProStrakan from which the business emerged strongly having reached the £100m turnover milestone for the first time, assisted considerably by the £8.1m US approval milestone for Fortesta. The Company recorded its first ever profit at both EBITDA and EBIT levels and achieved two US product approvals.

It was undoubtedly a year of two contrasting halves as the business flourished in the first six months of the year, with Abstral displaying continued strong growth in Europe and contributing to an EBITDA positive first half. However the second half of the year began less encouragingly with ongoing approval delays to both Fortesta and Abstral in the US and an interruption in manufacturing for Sancuso in the US. By the end of the year, thanks to the persistence and diligence of the team at ProStrakan and our partners, we responded successfully to these challenges, achieving the US approval of Fortesta and the recommencement of Sancuso's manufacture. The US approval of Abstral followed in the early days of January 2011. Our US partner for Fortesta, Endo Pharmaceuticals Inc. ("Endo"), launched Fortesta at the end of February 2011 and we will shortly launch Abstral through our own US sales force.

In addition, we announced in December a new strategic relationship with Paladin Labs Inc. ("Paladin") of Canada which saw Paladin adopt ProStrakan's existing £50.0m secured debt facility, now denominated in Canadian dollars, with the addition of certain conversion rights, and extending any capital repayments due on the facility until 2014. As part of the agreement, approved by shareholders in January 2011, Paladin have been granted the exclusive option to distribute all of ProStrakan's products in certain territories including Canada, Latin America, Sub-Saharan Africa and Israel.

We also saw board changes at ProStrakan, with the Group's Chief Executive, Dr Wilson Totten, resigning from ProStrakan in September. I took on the additional role of Acting Chief Executive upon Wilson Totten's resignation and, on behalf of the whole Board I would like to take this opportunity to acknowledge the significant role that he has played in the development of ProStrakan during his time with the company. Since the end of 2010, Jonathan Goodman, Chief Executive of Paladin, has joined the Board of Directors of ProStrakan, as a consequence of our new strategic relationship with Paladin, and I would also like to welcome Jonathan to the Board.

Since the turn of the year, the Board has received an offer from Japanese pharmaceutical company, Kyowa Hakko Kirin Co., Ltd. ("KHK"), to acquire ProStrakan and the Board of ProStrakan has recommended that shareholders accept this offer. This process is ongoing and, assuming it is approved by shareholders, ProStrakan's acquisition by KHK will mark a new chapter in the ProStrakan story which, I believe, will be beneficial to all concerned – shareholders and staff alike.

This proposed transaction is being made through a Scheme of Arrangement and the Scheme Document was posted to ProStrakan shareholders on 8 March 2011. There will be a court meeting and general meeting of shareholders on 31 March 2011 with the transaction expected to complete on or around 21 April 2011, subject to certain conditions outlined in the Scheme Document.

ProStrakan's progress thus far, and specifically in the face of significant challenges during 2010 is a testament to the hard work, energy and enthusiasm of its people, at head office, across Europe and in the US, and I wish to record the Board's thanks and admiration for the manner in which our people

have risen to these challenges. They have achieved a great deal, of which they can be justifiably proud.

## **BUSINESS REVIEW**

### **Overview**

ProStrakan completed 2010 strongly as it pushed through the £100m revenue mark and received two key product approvals in the US.

This result demonstrates success in fulfilling the Group's strategy of in-licensing and developing late-stage, patient-friendly products for unmet medical needs; promoting these products through our own sales forces in Europe and the US; and out-licensing these products to high quality partners in non-core areas.

The Group made significant progress in each of these three key areas. It demonstrated success in developing Abstral in the US by working closely with the US Food and Drug Administration ("FDA") in meeting its requirements for a Risk Evaluation and Mitigation Strategy ("REMS") programme, so enabling approval to be made in early January 2011. The Group successfully promoted its existing products in its EU and US markets, making particular progress in Europe through the success of Abstral, which grew significantly in its first full year of commercial availability. Finally it created significant value by working closely with Endo, its partner in the US for Fortesta, which was approved by the FDA late in the year and triggered a significant registration milestone.

Total revenues for 2010 increased by 27% (29% at constant currency) to £100.2m (2009: £79.0m). Included within this, product sales grew by 20% (22% at constant currency) to £89.2m (2009: £74.4m). Other income, from licensing and royalty receipts, grew by 140% to £11.0m (2009: £4.6m) helped largely by the £8.1m (\$12.5m) milestone payment receivable from Endo upon the approval of Fortesta. ProStrakan saw further growth from its portfolio of European products, continued growth from Abstral in Europe and another strong growth performance from Adcal-D3 in the UK. The US business grew sales of Sancuso prior to the reduced stock availability due to the interruption in its manufacturing in October. Partnering income increased significantly due to both increased product sales to business partners and increasing income from license receipts including the milestone from Endo discussed above.

The revenue growth helped improve profitability considerably and after posting its first ever EBITDA positive performance in the six months to 30 June 2010, the Group concluded the year positively by being profitable at both EBITDA and EBIT levels for the full year. Full year EBITDA was £10.8m for 2010 compared with a loss of £5.1m in 2009 and operating profit was £6.1m compared to a loss of £9.6m in 2009.

### **Segmental Revenue Analysis**

The business is managed on a geographical basis and has three key operating segments around which the Board and management run the business. These operating segments are Europe, the US, and Partnering Income, each of which is considered separately.

#### **Europe**

ProStrakan's European specialty pharmaceuticals business continued to be the principal driver of revenues for the Group in 2010.

Total European revenues in 2010 grew by 21% to £80.0m (2009: £66.5m). Approximately 45% of the Group's European revenues arise in the UK, with the majority of the remainder being Euro denominated incomes. Accordingly, foreign exchange movements can impact reported growth rates. Compared to 2009, Sterling strengthened slightly against the Euro in 2010, which reduced the reported growth rates within Europe. Excluding the impact of foreign currency fluctuations, revenue growth in Europe was 23%.

ProStrakan has a broad-based marketing and distribution capability across Europe and the company's products are promoted through its own sales forces in the UK, Germany, France, Spain and Italy. The Company also has marketing and distribution operations in Belgium, Holland, Luxembourg and Greece and a joint venture covering the Nordic region. Each country promotes a range of products, some of which are local to the specific country and referred to as "local products", whilst others are considered "Group products" as they are promoted in several different countries. Each of these Group products are reviewed in detail later in this report. Much of the revenue growth seen in Europe during 2010 came from the success of these Group products, benefiting from the increasing promotion and focus of the countries.

ProStrakan's biggest European business is the UK. The UK business experienced double digit growth due to good performance in several of its key products. Key local products include Adcal-D3 which is the market leading branded calcium and vitamin D3 oral supplement, used as an adjunct to specific therapy for the treatment of osteoporosis. Adcal-D3 is still ProStrakan's best-selling product and revenues grew by a further 14% in 2010 to £23.2m (2009: £20.4m). In addition, the UK business also markets Isotard XL, a once-daily prophylactic treatment for angina. Good growth was seen in all other Group products sold in the UK, with Abstral and Rectogesic making a significant contribution to revenues.

Spain is the Group's second biggest European business. Spain also achieved double digit growth, with the increased revenues coming entirely from sales of Group products – primarily Abstral and Rectogesic. Local products include Pencial, indicated for the treatment of advanced prostate cancer and Tebetane, indicated for the treatment of mild benign prostatic hyperplasia. The growth of local products in Spain was impacted by government price reduction measures introduced in the second half of 2010 which reduced growth. During 2010 the company in-licensed three new country-specific products for the Spanish market: Radiocare; Dragul; and Devazol, products operating in oncology and urology which complement the activities of the sales force.

The Group's French business grew strongly during 2010. The key driver of growth was Abstral which performed very strongly and greatly increased the sales of Group products in that market. Local product sales reduced. The main local product is Insuplant, indicated for diabetes and when the use of an implantable insulin pump is indicated. Sales of this product are coming to an end as the technology used to deliver the insulin is being phased out.

In Germany, revenue growth was modest, partly due to lost revenues from two local products which were disposed of in 2009. Group product sales were strong again heavily influenced by sales of Abstral. The business completed a re-organisation during 2010 including a relocation of its office.

Other smaller European businesses also performed well. Italy saw excellent growth as the business entered its first full year of commercial operations, following its launch in 2009. The Italian business launched CD2, a treatment for oral mucositis, in January 2011 in its local market. Operations in the Netherlands performed well with increased sales from Tostran and local products. The Group's joint

venture in Scandinavia performed well as we commenced rolling out Abstral across other Scandinavian countries during 2010, following its launch in Sweden in 2008.

## **United States**

In the last two years ProStrakan has expanded into the US, initially in the field of oncology support. 2010 US revenues were £6.8m compared with £7.3m in 2009, down 8% (down 9% at constant currency). All US revenues were generated by sales of Sancuso transdermal patch, and this performance was heavily impacted by a stock-out of Sancuso, now resolved, which greatly affected sales in the second half of 2010.

Sancuso has received considerable focus since its launch at the end of 2008 including the introduction of a number of initiatives designed to invigorate growth. These have included the launch of a specialty pharmacies distribution strategy; the introduction of a new co-pay assistance card; and a sharpened focus on specialist oncology hospitals and clinics with our primary target of achieving formulary or clinical pathway status for Sancuso. Sancuso's resultant performance in the first six months of 2010 also demonstrated growth of 28% over the second half of 2009.

In October 2010, stocks of Sancuso were exhausted following the decision by Aveva Drug Delivery Systems ("Aveva"), the manufacturer of Sancuso, to temporarily cease all manufacturing at its Florida facility in order to make changes to its own internal quality assurance systems. Aveva recommenced manufacture of Sancuso in December 2010 and ProStrakan recommenced distribution of this product at the end of January 2011. This supply interruption had an inevitable impact on revenues for Sancuso during 2010 and revenues for Sancuso in the second half of 2010 were only £2.2m (H2 2009: £3.6m).

Our strategy going forward includes an increased focus on oncologists that specialise in head and neck cancer, where the swallowing of tablets can be particularly difficult for patients. These initiatives have been supported by the launch of a suite of Sancuso promotional and instructional videos on YouTube, which are proving of interest to medical specialists and patients alike.

ProStrakan's US operation is headquartered in Bedminster, New Jersey. The US business focuses on sales & marketing, late stage development and marketed product support and currently accesses the US market via a sales force focused around major metropolitan areas across the US. This sales force focuses on oncologists and oncology support staff. In January 2011 the members of the US sales force became employees of ProStrakan, having previously been contracted through NovaQuest (Quintiles).

On 10 January 2011, ProStrakan announced the FDA approval of Abstral (for the management of breakthrough pain in cancer patients who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain).

Abstral will be launched in the US shortly and will be the only rapidly disintegrating sublingual tablet for breakthrough cancer pain on the US market, where the overall annual market value for immediate release fentanyl products is \$550m (Source: Wolters Kluwer, August 2010 MAT).

The combination of resumed manufacturing for Sancuso, and the approval of Abstral means that both products will be promoted from the second quarter of 2011 onwards.

## **Business Partnering**

Alongside ProStrakan's European and US sales and marketing operations, the third strand of ProStrakan's growth strategy is focused on capitalising on its high value medicines in non-core territories by entering into out-licensing arrangements with high quality partners with strong distribution capabilities in those markets. Partnering income increased in 2010 to £13.4m in comparison with 2009 (£5.2m), boosted significantly by the £8.1m US approval milestone for Fortesta.

Partnering income is made up of two types of revenue stream. Licensing income, together with royalties, made up a major component. Licensing income arises from third party distribution agreements entered into with business partners which often involves specific payments being made upon deal signature, receipt of registration, and or subsequent milestone payments once certain performance conditions are met. In addition to this, partnering agreements then require ProStrakan to source and manufacture stock which ProStrakan sells to business partners at an agreed price for them to then sell to customers in the relevant country markets.

Total revenues from Licensing including milestones and royalties were £11.0m (2009: £4.6m). The highlight in licensing activities in 2010 was the receipt, in December 2010, of an approval milestone of £8.1m (\$12.5m) for Fortesta received from our US partner, Endo. Endo launched Fortesta (branded as Tostran, Tostrex, Ilnogen and Fortigel in Europe, where it is marketed by ProStrakan) in February 2011. ProStrakan will exclusively supply Fortesta to Endo for the US and will receive an undisclosed royalty rate on sales generated there.

Also during 2010, Partnering income included a further £2.4m of product sales (2009: £0.6m), which included sales of Abstral, Xomolix, Rectogesic, Tostran and Sancuso to business partners. The largest single growth item within this was from Abstral sales which included sales to Gedeon Richter in respect of Central and Eastern Europe.

ProStrakan has a small but growing team dedicated to starting and managing these alliances. Notable events for this team during 2010 included the following:

- First product shipments of Sancuso to South Korea and Singapore
- Abstral launched in four of the seven CEE countries to which it has been out-licensed
- Five product launches through partners
- 13 regulatory approvals through partners for ProStrakan products

Bayer Schering Pharma has informed ProStrakan that it is handing back the right to develop and commercialise Tostran in 65 countries worldwide. The Group has also received notification that Solasia Pharma KK is handing back the rights to market and sell Sancuso in Japan, but that it will retain its rights in the other territories for which it has an interest. Any monies received to date from either partner are non refundable.

In December 2010 the Group announced that it proposed to enter into a new strategic relationship with Paladin which provided them with an exclusive option to distribute certain of ProStrakan's products for Canada and certain emerging territories. This agreement builds on the relationship which already exists between the two companies under which Paladin has already in-licensed the rights to distribute Abstral and Sancuso in Canada. The new agreement, which was approved by shareholders in January 2011, broadens this existing partnership, with Paladin being granted exclusive option to distribute all of ProStrakan's products, including Abstral, Sancuso, Rectogesic, Xomolix and Tostran, in certain specific territories for which ProStrakan does not already have distribution agreements.

These territories include: Canada, Latin America, Sub-Saharan Africa and Israel. Terms of the licence agreements are not disclosed but equate to arm's length commercial arrangements. In addition, Paladin will have the right for a certain period to license any new products acquired or licensed by ProStrakan for those same territories and on the same terms and conditions. Since the year end, Paladin has received approval for Abstral in Canada.

## **Group Products**

ProStrakan has five core products which it markets and distributes widely across the Group, whether in Europe, the US or via business partners in the rest of the world. As detailed earlier, these five core products are increasingly receiving the majority of our focus in channeling the Group's sales and marketing resources. Sales from these products grew by over 40% versus 2009 and generated the majority of the overall growth seen in ProStrakan's product sales.

**Abstral** is a new, sub-lingual (under the tongue) formulation of fentanyl, a long-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for their chronic pain, licensed from Orexo AB in Sweden.

Abstral was launched in Sweden in August 2008 and in the UK, Germany, France and Spain during 2009. Abstral was launched in Italy in August 2010. Abstral was also launched in Norway, through our joint venture with Orexo AB. Abstral also generates significant revenues from sales to business partners in CEE, Canada, Slovenia and Ireland. In 2010, Abstral achieved sales across all areas of £17.3m (2009: £5.8m).

**Rectogesic** is indicated for the relief of pain associated with chronic anal fissure. This product is sold in Europe and by business partners in Turkey, Ireland, Israel and Slovenia. The product recorded further strong growth during 2010, with sales increasing to £9.3m (2009: £8.1m).

**Xomolix** (also branded as Droperidol) is a branded, injectable drug used primarily in hospitals for the prevention and treatment of post-operative nausea and vomiting. It is sold in Europe and by business partners. Total revenues grew to £7.8m during 2010 (2009: £7.5m).

**Tostran** (also branded as Tostrex, Itnogen, Fortigel and Fortesta) is a transdermal testosterone gel that utilises a metered dose delivery system for testosterone replacement therapy in male hypogonadism. This product is sold in Europe and by business partners, and was recently approved for sale in the US by our business partner there. 2010 saw sales of this product increase to £3.3m (2009: £2.1m) which included initial deliveries to Endo, our US partner.

**Sancuso** is a transdermal patch that delivers granisetron, an established 5-HT<sub>3</sub> receptor antagonist, steadily into the bloodstream for up to seven days. It helps to prevent the side-effects of nausea and vomiting in patients undergoing chemotherapy (CINV) for up to five consecutive days, without the need for daily injections or having to swallow pills. The majority of revenues are generated from sales by ProStrakan in the US, however revenues were also received from sales by business partners in various Asian markets. Total revenues were £6.8m during 2010 (2009: £7.3m).

## **Product Development**

The main driver of activity during 2010 was focused on the approval of Abstral in the US which was successfully achieved in early January 2011. This product was initially expected to receive approval in

June 2010 however the FDA announced in early June 2010 that it planned to extend the review period for Abstral.

This product is the first product to be approved in the US with the FDA mandated class-wide REMS for transmucosal immediate release fentanyl products. The Abstral REMS allows appropriate prescriptions to be filled at retail pharmacies as well as providing access to Abstral within hospitals.

The Group received a complete response from the FDA for Rectogesic in the US on 1 April 2010. This response concerned the statistical significance of pain relief demonstrated by the clinical trial data. The business entered into detailed discussions with the FDA over the most appropriate statistical analysis for a product treating the pain associated with chronic anal fissure. Following this, further work was done and on, 21 December 2010, ProStrakan re-filed Rectogesic (0.4% nitroglycerin ointment) for the treatment of pain associated with chronic anal fissure. The PDUFA goal date for this review is at the end of June 2011.

Following discussions with the European regulatory bodies over the registration of Sancuso in Europe, ProStrakan has re-filed Sancuso in the EU and this re-filing has been validated and approval is anticipated for this product in Q4 2011.

### **Manufacturing**

ProStrakan outsources all of its manufacturing operations to third party suppliers. It employs a core team at its corporate headquarters in Galashiels which manages these relationships and makes strategic decisions as to the most appropriate suppliers to use for each product in each market.

The team works closely with existing suppliers to maintain quality levels, ensure continuity of supply, influence pricing levels and control stock. The business is currently managing several transfers of existing products to new suppliers for varying reasons including quality, continuity of supply and cost.

In October 2010 the business experienced a major product interruption in the supply of its Sancuso transdermal patch product. This interruption was caused by Aveva, the manufacturer of Sancuso, ceasing all manufacturing at its Florida facility in order to make changes to its own internal quality assurance systems. This resulted in customers being without product for part of 2010. Aveva recommenced manufacture of Sancuso in December 2010 and ProStrakan restarted distribution of this product at the end of January 2011. The business is working closely with Aveva in order to ensure future continuity of supply.

### **Other Financial Items**

#### **Gross profit**

Gross profit increased to £67.4m (2009: £52.6m), an increase of 28% over the prior year. The increase in gross profit was a result of the growth in product sales and the milestone receivable as a result of the Fortesta approval. Gross margins were consistent with the prior year at 67%. This stable margin comprised a number of moving parts such as product cost savings delivered by the manufacturing team, the impact of government price cuts in certain EU markets, and product mix including the impact of higher levels of milestone receipts.

#### **Operating costs**

Operating costs decreased by 4% to £56.6m (2009: £58.8m). Within this, distribution costs saw a 6% increase as the Group invested in its selling and marketing activities. Distribution costs comprise the

selling, marketing and distribution costs of the Group's commercial teams and increases here reflect on-going investment in the European Abstral brand, coupled with tight cost control in the US commercial operations to reduce the impact on profit of the Sancuso supply issue outlined above. Administration costs increased by 12% to £8.5m (2009: £7.6m), this increase being a result of one off project costs of £0.6m offset by a credit in respect of share-based payments contained within the 2009 overheads. Development costs decreased by 44% to £6.7m (2009: £12.0m) as a result of reduced clinical trial work on the Group's portfolio. This reduction reflected that the Group had several new drug application dossiers in preparation during 2009 and that efforts were concentrated on certain post approval commitments for Sancuso in the US. During 2010 the focus shifted to helping manage those new drug applications through the regulatory process. Foreign exchange movements had the impact of marginally reducing the sterling equivalent cost of overseas operations compared to prior year.

### **Other gains/losses**

Other gains were £nil (2009: £1.1m) with gains in the prior year arising from the sale of three non-core products in Europe.

### **EBITDA and Operating Profit**

As a result of the increased revenues and reduced overheads discussed above ProStrakan is pleased to report a positive EBITDA of £10.8m for the full year against an EBITDA loss of £5.1m for 2009. This is the first ever full year profit recorded at the EBITDA level and follows the maiden positive EBITDA reported in the unaudited results for the first half of the year.

Depreciation, amortisation and impairment costs increased by 4% to £4.7m (2009: £4.5m). 2010 includes an impairment charge of £0.7m (2009: £0.3m) in respect of writing down the book value of certain acquired technology which the Group is no longer likely to commercialise.

2010 reported operating profit £6.1m (2009: loss £9.6m) and demonstrates progress in the previously stated objective of firmly focusing on growing the business profitably.

### **Net Finance Costs and Taxation**

Net finance costs including changes in fair value of warrants increased to £6.7m (2009: £5.4m). This was due to a combination of increased borrowing levels, a higher blended interest rate on the borrowings and a £0.4m charge (2009: £0.2m charge) in respect of changes to the fair value of warrants issued to the lenders in March 2007.

Taxation charges for the year were £0.4m (2009: £0.6m), including a £0.3m (2009: £0.5m) movement in the deferred tax assets created in 2008 and local corporation taxes payable. The Group has significant carried forward losses available to be offset against future operating profits.

### **Recognised loss for the financial year**

The loss from continuing operations was £1.0m (2009: £15.6m). As discussed previously the significant improvement was as a result of increased revenues from Group products and reduced overhead increases compared to previous years.

### **Loan Facility and refinancing**

During 2010 the Group continued its borrowing relationship with Fortress Investment Group, Morgan Stanley and Och-Ziff Capital Management Group. In April 2010, a further £8.0m was drawn from the facility bringing the total amount drawn to £46.6m. In line with the facility agreement the Group made a £0.2m repayment to the lenders during the year in relation to certain licensing activities together with

the first £1.0m capital repayment in December 2010 making the total amount drawn £45.4m at 31 December 2010.

On 7 January 2011 at a general meeting of the company, shareholders approved the assignment of the Company's debt facility to Paladin and the assignment was completed on 12 January 2011. This included the conversion of the facility into Canadian dollars. In addition to the facility being assigned to Paladin, the facility was amended so that Paladin has a right, from July 2011, to convert all or part of the facility into ordinary share capital at £1.10 per share. Capital repayments are not due to commence until January 2014 at which point the value of the facility not converted is re-payable. The rate of interest on the revised facility is 10.5% compared with a blended rate of 11.9% on the original facility. The Group took the opportunity to draw additional funds from the facility as part of the assignment and, after fees, accrued interest and an early termination payment to the original lenders totalling £2.2m, the Group received a further £2.4m from the facility.

In addition to the assignment Paladin and the Group entered into an exclusive distribution and licence agreement in relation to the commercialisation of certain of ProStrakan's products in various territories (Canada / Latin America, Sub-Saharan Africa and Israel.)

### **Cash Flow**

Cash flow from continuing operations was an outflow of £0.7m versus an outflow of £7.2m during 2009, reflecting the improved trading position of the Group. The milestone from Endo, relating to the US approval of Abstral, was received in January 2011 and is therefore not reflected in the 2010 cash flows.

During the first half of 2010 the Group drew down £8.0m in capital from its debt provider, in December the Group made its first capital re-payment of £1.0m in line with the credit facility and a further £0.2m of re-payments to the lenders in relation to certain licensing activity during the year.

The items discussed above resulted in a £0.3m decrease in cash and cash equivalents during the year (2009: £17.1m decrease) which when combined with the impact of exchange losses, produced a closing cash balance of £19.4m (2009: £19.0m).

### **Balance Sheet**

The Group's non-current assets at 31 December 2010 were £35.5m (2009: £40.2m). This total included intangible assets of £32.5m (2009: £36.7m) which comprised acquired product rights £22.2m (2009: £26.5m), goodwill £9.7m (2009: £10.0m) and other intangibles £0.6m (2009: £0.2m). Net current assets have decreased slightly due to an increase in trade and other receivables being offset by near term capital re-payments of £12.0m under the old loan facility which has since been delayed to January 2014 as part of the refinancing discussed above. Total borrowings increased to £44.4m (2009: £36.5m) and include funds drawn-down from lenders, less the value of cumulative accretion of loan warrants and the carrying value of facility set up costs. The balance sheet as at 31 December 2010 reflects the lending relationship that was in place at that time, with the arrangements with Paladin having been put in place in early January 2011 and as such having no impact in the closing balance sheet for 2010. The total equity position as at 31 December 2010 was negative £6.2m compared to a negative balance of £5.5m at 31 December 2009.

### **OUTLOOK**

ProStrakan is now well-positioned to make the next step forward in its development. Fortesta was launched by Endo at the end of last month; Abstral will be introduced to the US oncology support

market through our own US sales force shortly and Sancuso is already re-establishing itself in this market. We continue to develop our European business, with continued focus on Abstral and on capitalising on the market positions of our other European products. Our business partnering team continue to seek out opportunities to generate revenues.

Meanwhile the offer from KHK to acquire ProStrakan at a significant premium will be considered by ProStrakan shareholders at a court meeting and a general meeting on 31 March 2011. Subject to shareholder and certain other approvals outlined in the Scheme Document, ProStrakan will become the European and US divisions of a significant pharmaceutical business that owns and develops a large and attractive portfolio of pipeline products in various therapeutic areas.

Peter Allen  
Chairman & Acting Chief Executive  
ProStrakan Group plc  
17 March 2011

# Consolidated income statement (audited)

for the year ended 31 December 2010

	Year ended 31 December 2010 £m	Year ended 31 December 2009 £m
Revenue	100.2	79.0
Cost of goods sold	(32.8)	(26.4)
<b>Gross profit</b>	<b>67.4</b>	<b>52.6</b>
Distribution costs	(41.4)	(39.2)
Administrative expenses	(8.5)	(7.6)
Development	(6.7)	(12.0)
Other gains – net	-	1.1
<b>Earnings before interest, taxation, depreciation and amortisation</b>	<b>10.8</b>	<b>(5.1)</b>
Depreciation, amortisation and impairment charges	(4.7)	(4.5)
<b>Operating profit/(loss)</b>	<b>6.1</b>	<b>(9.6)</b>
Finance income	0.1	0.2
Finance costs	(6.4)	(5.4)
Movement in fair value of warrants	(0.4)	(0.2)
<b>Loss before income tax</b>	<b>(0.6)</b>	<b>(15.0)</b>
Taxation	(0.4)	(0.6)
<b>Loss for the year from continuing operations</b>	<b>(1.0)</b>	<b>(15.6)</b>
<b>Discontinued operations</b>	<b>-</b>	<b>(0.2)</b>
<b>Loss for the year</b>	<b>(1.0)</b>	<b>(15.8)</b>
Earnings per share for loss attributable to the equity holders of the Company during the year		
Basic and diluted earnings per share (expressed in pence per share)		
From continuing operations	(0.5)	(7.7)
From discontinued operations	-	(0.1)
	(0.5)	(7.8)

# Consolidated statement of comprehensive income (audited)

for the year ended 31 December 2010

	Year ended 31 December 2010 £m	Year ended 31 December 2009 £m
Loss for the year	(1.0)	(15.8)
Currency translation differences	-	2.5
<b>Total comprehensive income for the period, net of tax</b>	<b>(1.0)</b>	<b>(13.3)</b>

# Balance sheet (audited)

as at 31 December 2010

	Group 31 December 2010 £m	Group 31 December 2009 £m	Company 31 December 2010 £m	Company 31 December 2009 £m
<b>Assets</b>				
<b>Non-current assets</b>				
Investment in subsidiaries	-	-	150.1	146.0
Intangible assets	32.5	36.7	-	-
Property, plant and equipment	1.1	1.2	-	-
Deferred tax assets	1.9	2.3	-	-
	35.5	40.2	150.1	146.0
<b>Current assets</b>				
Inventories	7.3	6.1	-	-
Trade and other receivables	23.7	12.8	0.2	0.6
Research and development tax credits receivable	0.1	-	-	-
Cash and cash equivalents	19.4	19.0	14.5	17.1
	50.5	37.9	14.7	17.7
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables	26.0	23.7	77.3	71.7
Provision for other liabilities and charges	0.8	0.4	-	-
Borrowings	12.0	1.0	-	-
Warrant liability	2.8	2.4	-	-
	41.6	27.5	77.3	71.7
<b>Net current assets/(liabilities)</b>	<b>8.9</b>	<b>10.4</b>	<b>(62.6)</b>	<b>(54.0)</b>
<b>Non-current liabilities</b>				
Other non-current liabilities	18.2	20.6	-	-
Borrowings	32.4	35.5	-	-
	50.6	56.1	-	-
<b>Net (liabilities)/assets</b>	<b>(6.2)</b>	<b>(5.5)</b>	<b>87.5</b>	<b>92.0</b>
<b>EQUITY</b>				
<b>Capital and reserves attributable to the Company's equity holders</b>				
Share capital	172.6	172.3	172.1	171.6
Other reserves	71.5	71.5	63.3	63.2
Retained earnings	(250.3)	(249.3)	(147.9)	(142.8)
<b>Total equity</b>	<b>(6.2)</b>	<b>(5.5)</b>	<b>87.5</b>	<b>92.0</b>

# Consolidated statement of changes in equity (audited)

for the year ended 31 December 2010

	Share capital £m	Other reserves £m	Retained earnings £m	Total equity £m
<b>Balance at 1 January 2009</b>	<b>172.2</b>	<b>69.9</b>	<b>(233.5)</b>	<b>8.6</b>
Other comprehensive income:				
Loss for the year	-	-	(15.8)	(15.8)
Currency translation difference	-	2.5	-	2.5
Total comprehensive income for the year	-	2.5	(15.8)	(13.3)
Transactions with owners:				
Employee share option scheme:				
- value of services provided	-	0.4	-	0.4
- leavers during year	-	(1.4)	-	(1.4)
- warrants issued	-	0.1	-	0.1
- options exercised	0.1	-	-	0.1
	0.1	(0.9)	-	(0.8)
<b>Balance at 31 December 2009</b>	<b>172.3</b>	<b>71.5</b>	<b>(249.3)</b>	<b>(5.5)</b>
<b>Balance at 1 January 2010</b>	<b>172.3</b>	<b>71.5</b>	<b>(249.3)</b>	<b>(5.5)</b>
Other comprehensive income:				
Loss for the year	-	-	(1.0)	(1.0)
Currency translation difference	-	-	-	-
Total comprehensive income for the year	-	-	(1.0)	(1.0)
Transactions with owners:				
Employee share option scheme:				
- value of services provided	-	0.6	-	0.6
- leavers during the year	-	(0.2)	-	(0.2)
Shares issued	0.4	(0.4)	-	-
Purchase of own shares by ESOP	(0.1)	-	-	(0.1)
	0.3	-	-	0.3
<b>Balance at 31 December 2010</b>	<b>172.6</b>	<b>71.5</b>	<b>(250.3)</b>	<b>(6.2)</b>

# Statement of cash flows (audited)

for the year ended 31 December 2010

	Group Year ended 31 December 2010 £m	Group Year ended 31 December 2009 £m	Company Year ended 31 December 2010 £m	Company Year ended 31 December 2009 £m
<b>Cash (used)/generated from operating activities</b>				
<b>Continuing operations</b>	(0.7)	(7.2)	(1.8)	14.3
<b>Discontinued operations</b>	-	(7.8)	-	(7.8)
<b>Cash (used)/generated in operating activities</b>	(0.7)	(15.0)	(1.8)	6.5
<b>Continuing operations:</b>				
Taxation paid	(0.1)	-	-	-
Finance income	0.1	0.2	0.2	0.2
Finance cost	(5.2)	(4.2)	(1.0)	(1.7)
	(5.2)	(4.0)	(0.8)	(1.5)
<b>Net cash (used)/generated in operating activities</b>	(5.9)	(19.0)	(2.6)	5.0
<b>Cash flows from investing activities</b>				
Purchase of intangible assets	(0.9)	(1.0)	-	-
Purchases of property, plant and equipment	(0.2)	(0.1)	-	-
Proceeds from sale of intangibles	-	1.4	-	-
<b>Cash flows (used)/generated in continuing operations – investing activities</b>	(1.1)	0.3	-	-
<b>Cash flows from financing activities</b>				
Proceeds from borrowings	7.9	5.0	-	-
Borrowings repaid	(1.2)	(3.4)	-	-
<b>Net cash generated by financing activities</b>	6.7	1.6	-	-
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(0.3)</b>	<b>(17.1)</b>	<b>(2.6)</b>	<b>5.0</b>
Cash and cash equivalents at the beginning of the year	19.0	34.7	17.1	12.1
Exchange gains on cash and cash equivalents	0.7	1.4	-	-
<b>Cash and cash equivalents at the end of the year</b>	<b>19.4</b>	<b>19.0</b>	<b>14.5</b>	<b>17.1</b>

## **1. Notes**

### **a. Basis of preparation**

The financial statements have been prepared in accordance with the Group's accounting policies which are based on International Financial Reporting Standards ("IFRS") and IFRIC interpretations endorsed by the European Union ("EU") and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

The consolidated financial statements are presented in pounds sterling and all values are rounded to the nearest million (£'000'000), except when otherwise indicated.

The financial information for the years ended 31 December 2010 and 2009 set out above does not constitute statutory accounts within the meaning of section 435 of the Companies Act 2006 ("the Act"). Statutory accounts for the year ended 31 December 2009 have been delivered to the Registrar of Companies, and the accounts for the year ended 31 December 2010 will be delivered to the Registrar of Companies following the Annual General Meeting. The auditors have reported on those accounts; their reports were (i) unqualified, (ii) did not include any reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report and (iii) did not contain a statement under section 498(2) or section 498(3) of the Companies Act 2006.

The Annual Report and Accounts for the year ended 31 December 2010 will be posted to shareholders in advance of the Annual General Meeting which is due to be held on 26 May 2011. The results for 2010 were approved by the Board of Directors on 17 March 2011 and are audited.

Interim and preliminary announcements notified to the London Stock Exchange are available on the internet at [www.prostrakan.com](http://www.prostrakan.com).

### **b. Going concern**

As part of the year end accounts exercise, the Directors are required to satisfy themselves that it is reasonable for them to conclude whether it is appropriate to prepare financial statements on a going concern basis. The Directors of the Group have reviewed various aspects of the business including budget plans covering the periods for at least twelve months from the date of approval of the accounts, taking account of reasonably possible changes in trading performance, the current and forecast debt position, related covenants, other sources of capital and various external factors. Notwithstanding the Group's negative net asset position as at 31 December 2010, the Directors are satisfied after making these enquiries that the Group has adequate resources to continue in business for the foreseeable future and, accordingly, consider that it is appropriate to adopt the going concern basis in preparing this full year financial information.

## 2. Segmental information

The chief operating decision-maker has been identified as the Board of Directors. The Board reviews the Group's internal reporting in order to assess performance and allocate resources. Management has determined the operating segments based on these reports.

The Board considers the business from a geographic perspective and assesses the performance of UK, EU (excluding the UK), US and Partnering income.

The Board assesses the performance of the operating segments based on a measure of adjusted earnings before interest, tax, depreciation and amortisation (EBITDA). This measurement basis excludes the effects of non-recurring expenditure from the operating segments. Finance income and expenditure are not included in the result for each operating segment that is reviewed by the Board. Other information provided to the Board is measured in a manner consistent with that in the financial statements

Total assets exclude cash and cash equivalents which are managed on a central basis. These are part of the reconciliation to total balance sheet assets.

	2010 £m	2009 £m
<b>Revenue</b>		
UK	35.9	31.7
EU (excluding the UK)	44.1	34.8
Total European	80.0	66.5
US	6.8	7.3
Partnering income	13.4	5.2
	100.2	79.0
<b>Earnings before interest, taxation, depreciation and amortisation</b>		
UK	(1.3)	(0.1)
EU (excluding the UK)	8.4	(0.5)
Total European	7.1	(0.6)
US	(4.8)	(3.4)
Partnering income	8.5	(1.1)
	10.8	(5.1)
A reconciliation of total EBITDA is provided as follows:		
	2010 £m	2009 £m
EBITDA	10.8	(5.1)
Depreciation, amortisation and impairment charges	(4.7)	(4.5)
Finance income	0.1	0.2
Finance cost	(6.4)	(5.4)
Revaluation of warrants	(0.4)	(0.2)
Discontinued operations	-	(0.2)
Taxation	(0.4)	(0.6)
Loss for the year	(1.0)	(15.8)

Total Assets:		
	2010	2009
	£m	£m
UK	6.2	6.0
EU (excluding UK)	23.0	23.4
Total EU	29.2	29.4
US	0.7	2.0
Partnering income	36.7	27.7
	66.6	59.1

Reportable segments' assets are reconciled to total assets as follows:

	2010	2009
	£m	£m
Total segment assets	66.6	59.1
Cash and cash equivalents	19.4	19.0
Total assets per balance sheet	86.0	78.1

Capital expenditure:

	2010	2009
	£m	£m
UK	0.2	0.2
EU (excluding the UK)	0.1	0.1
Total EU	0.3	0.3
US	0.1	-
Partnering income	0.7	0.8
	1.1	1.1

Analysis of revenue by category:

	2010	2009
	£m	£m
Product sales <sup>1</sup>	89.2	74.4
Licensing income	10.8	4.2
Royalty income	0.2	0.4
	100.2	79.0

<sup>1</sup> Product sales represents 89% of total revenues (2009: 94%)

### 3. Discontinued operations

On 2 July 2009 ProStrakan reported it had agreed to make a payment in cash of £7.8m (€9.15m) in full and final settlement with Aventis against a €13.4m tax liability, incurred by Aventis, arising from the sale of ProSkelia SAS ("ProSkelia") by ProStrakan in December 2006. This settlement resulted in an additional charge of £0.2m against amounts already provided, which has been included under discontinued operations.

	2010	2009
	£m	£m
Other losses	-	(0.2)
Loss for the year from discontinued operations	-	(0.2)

### 4. Other gains/(losses)

	2010	2009
	£m	£m
Other financial assets at fair value through profit or loss		
- income from grants	-	0.1
- profit on disposal of product rights <sup>1</sup>	-	1.0
	-	1.1

<sup>1</sup>The profit on disposal of product rights arose from the sale of three non core products from the Groups German subsidiary.

## 5. Finance income and costs

	2010 £m	2009 £m
<b>Finance income</b>		
Interest receivable on short-term deposits	0.1	0.2
Interest payable on bank borrowings	(5.2)	(4.2)
Accretion of warrants on debt facility	(0.7)	(0.8)
Amortisation of set-up costs on debt facility	(0.5)	(0.4)
<b>Finance cost</b>	<b>(6.4)</b>	<b>(5.4)</b>

## 6. Taxation

	2010 £m	2009 £m
Current tax:		
Income tax charge	0.1	0.1
Deferred tax:		
Deferred tax charge	0.3	0.5
Tax charge in income statement	0.4	0.6

The tax on the Group's losses before tax differs from the theoretical amount that would arise using the standard rate of corporation tax in the UK. The differences are explained below.

	2010 £m	2009 £m
Loss before tax – continuing activities	(0.6)	(15.0)
Loss before tax – discontinued activities	-	(0.2)
<b>Total</b>	<b>(0.6)</b>	<b>(15.2)</b>
Tax calculated at rate of corporation tax in the UK of 28% (2009: 28%)	(0.2)	(4.3)
Expenses not deductible for tax purposes	1.0	0.9
Change in unrecognised deferred tax asset	(1.6)	4.0
Recognised deferred tax rate change adjustment	1.2	-
Tax charge in income statement	0.4	0.6

## 7. Earnings per share

Basic earnings per share is calculated by dividing the loss attributable to ordinary shareholders by the weighted average number of ordinary shares in issue during the year, excluding those held in the Executive Share Option Plan (ESOP), which are treated as cancelled.

	As at 31 December 2010	As at 31 December 2009
Loss attributable to equity holders of the Company (£m)	(1.0)	(15.8)
Basic earnings per share (pence per share)	(0.5)	(7.8)
Basic earnings per share from continuing operations		
Loss attributable to equity holders of the Company (£m)	(1.0)	(15.6)
Basic earnings per share (pence per share)	(0.5)	(7.7)
Basic earnings per share from discontinued operations		
Loss attributable to equity holders of the Company (£m)	-	(0.2)
Basic earnings per share (pence per share)	-	(0.1)
Weighted average number of ordinary shares	202.1	201.3

Diluted

IAS 33 requires presentation of diluted earnings per share when a company could be called upon to issue shares that would decrease net profit or increase net loss per share. For a loss making company with outstanding dilutive potential ordinary shares, net loss per share would only be decreased by the exercise of such potential ordinary shares. Therefore diluted earnings per share is not presented.

## 8. Intangible assets

Group	Goodwill £m	Product rights £m	Other <sup>1</sup> £m	Total £m
<b>At 1 January 2010</b>				
Cost	10.0	51.1	1.0	62.1
Accumulated amortisation	-	(24.6)	(0.8)	(25.4)
<b>Net book value</b>	<b>10.0</b>	<b>26.5</b>	<b>0.2</b>	<b>36.7</b>
<b>Year ended 31 December 2010</b>				
Opening net book amount	10.0	26.5	0.2	36.7
Additions	-	0.3	0.6	0.9
Disposal	-	(0.1)	-	(0.1)
Amortisation charge	-	(3.6)	(0.1)	(3.7)
Impairment	-	(0.7)	-	(0.7)
Exchange differences	(0.3)	(0.2)	(0.1)	(0.6)
<b>Closing net book value</b>	<b>9.7</b>	<b>22.2</b>	<b>0.6</b>	<b>32.5</b>
<b>At 31 December 2010</b>				
Cost	9.7	50.1	1.5	61.3
Accumulated amortisation	-	(27.9)	(0.9)	(28.8)
<b>Net book value</b>	<b>9.7</b>	<b>22.2</b>	<b>0.6</b>	<b>32.5</b>
<b>At 1 January 2009</b>				
Cost	10.9	51.6	0.9	63.4
Accumulated amortisation	-	(21.0)	(0.7)	(21.7)
<b>Net book value</b>	<b>10.9</b>	<b>30.6</b>	<b>0.2</b>	<b>41.7</b>
<b>Year ended 31 December 2009</b>				
Opening net book amount	10.9	30.6	0.2	41.7
Additions	-	0.9	0.1	1.0
Disposals	-	(0.4)	-	(0.4)
Amortisation	-	(3.8)	(0.1)	(3.9)
Impairment	-	(0.3)	-	(0.3)
Exchange differences	(0.9)	(0.5)	-	(1.4)
<b>Closing net book value</b>	<b>10.0</b>	<b>26.5</b>	<b>0.2</b>	<b>36.7</b>
<b>At 31 December 2009</b>				
Cost	10.0	51.1	1.0	62.1
Accumulated amortisation	-	(24.6)	(0.8)	(25.4)
<b>Net book value</b>	<b>10.0</b>	<b>26.5</b>	<b>0.2</b>	<b>36.7</b>

<sup>1</sup> Other intangibles include software and other costs.

#### Impairment tests for goodwill

Goodwill arising from previous acquisitions is tested annually for impairment under IAS 36. No Goodwill impairment charges were required during the year. Goodwill is allocated to the Group's cash-generating units (CGUs) identified as follows:

- (a) Development is treated as a separate CGU.
- (b) Each commercial territory under the control and guidance of a General Manager is a CGU.

The goodwill arising from the acquisitions of Elfar SA and Arzneimittel Pharma GmbH as allocated to Spain and Germany Commercial respectively. The rationale for this is that the CGUs benefiting fundamentally from these acquisitions are these identifiable Groups and these CGUs are not larger than the Group's reported segments. The carrying amount of goodwill by division is as follows:

	Spain commercial £m	Germany commercial £m	Total £m
As at 1 January 2009	10.2	0.7	10.9
Exchange differences	(0.8)	(0.1)	(0.9)
As at 31 December 2009	9.4	0.6	10.0
As at 1 January 2010	9.4	0.6	10.0
Exchange differences	(0.4)	0.1	(0.3)
As at 31 December 2010	9.0	0.7	9.7

#### Measurement of recoverable amounts:

##### Spain and Germany Commercial

The value of the assets, being the ongoing trading of the Spanish and German Commercial CGUs, are valued on a discounted cash flow basis.

#### Key assumptions in the calculations are:

- (i) sales, gross margin and expenses based on approved budgets and forecasts for the next 10 years, being the average life of the products currently marketed;
- (ii) discount rates – 12%-14% pre tax, corresponding to the internal rate of return used within the Group; and
- (iii) growth rates – long term growth rates, in line with long term planning and forecasts, are assessed on an individual basis dependent on product portfolio maturity. Assumed rates are between 3% - 1% decreasing in outer years.

Management determined the budgeted gross margin based on past performance and its expectations for the market development. The weighted average growth rates used are consistent with the forecasts included in industry reports. The discount rates used are pre-tax and reflect specific risks relating to the relevant segments.

## 9. Property, plant and equipment

Group	Plant & equipment £m	Furniture & fittings £m	Total £m
At 1 January 2010			
Cost or valuation	0.9	1.6	2.5
Accumulated depreciation	(0.5)	(0.8)	(1.3)
<b>Net book value</b>	<b>0.4</b>	<b>0.8</b>	<b>1.2</b>
Year ended 31 December 2010			
Opening net book amount	0.4	0.8	1.2
Additions	0.2	-	0.2
Depreciation charge	(0.1)	(0.2)	(0.3)
<b>Closing net book value</b>	<b>0.5</b>	<b>0.6</b>	<b>1.1</b>
At 31 December 2010			
Cost or valuation	1.1	1.6	2.7
Accumulated depreciation	(0.6)	(1.0)	(1.6)
<b>Net book value</b>	<b>0.5</b>	<b>0.6</b>	<b>1.1</b>
At 1 January 2009			
Cost or valuation	0.8	1.6	2.4
Accumulated depreciation	(0.3)	(0.7)	(1.0)
<b>Net book value</b>	<b>0.5</b>	<b>0.9</b>	<b>1.4</b>
Year ended 31 December 2009			
Opening net book amount	0.5	0.9	1.4
Additions	0.1	-	0.1
Depreciation charge	(0.2)	(0.1)	(0.3)
<b>Closing net book value</b>	<b>0.4</b>	<b>0.8</b>	<b>1.2</b>
At 31 December 2009			
Cost or valuation	0.9	1.6	2.5
Accumulated depreciation	(0.5)	(0.8)	(1.3)
<b>Net book value</b>	<b>0.4</b>	<b>0.8</b>	<b>1.2</b>

## 10. Borrowings

On 27 March 2007 the Group entered into a £50 million debt facility with the initial advance being provided by funds managed by Fortress Investment Group, Morgan Stanley and funds managed by Och-Ziff Capital Management Group ("Fortress"). The administrative Agent is Morgan Stanley Bank International Limited. The debt facility is secured over the intellectual property of the Group and has strict requirements for drawing funds, compliance with covenants and reporting requirements.

Draw-down under the facility is made with reference to the level of sales from key products recorded by the Group in the previous twelve month period (borrowing base capability). The level of draw-down available at any one time is governed by financial covenants which define the minimum sales levels required versus year on year product growth targets and sales plans. Other financial covenants require that the Group must maintain a minimum cash level of £4.5m of which no more than £1.5m can be held by certain subsidiaries at any time. The Group is also required to provide regular monthly trading reports, as well as interim and full year accounts in a timely manner.

The Group drew down an additional £8.0m from the facility in April 2010 (£7.9m after fees) and repaid £0.1m in relation to the disposal of Zindaclin making the total amount drawn at the half-year of £46.5m. In the second half the Group re-paid a further £0.1m relating to the disposal of Zindaclin and made the first £1.0m capital repayment in December 2010 making the amount drawn at 31 December £45.4m.

Under the terms of the facility, interest is repaid on a monthly basis, with capital repayments due to commence in December 2010. From that time the Group will repay £1.0m per month until the end of February 2012, at which point the outstanding capital sum will be repaid in full.

The maturity of the amount drawn down as at 31 December 2010 is detailed below:

	2010 £m	2009 £m
Current	12.0	1.0
1-5 years	33.4	37.6
<b>Total</b>	<b>45.4</b>	<b>38.6</b>

Interest on the amount drawn is charged at a rate of (i) the greater of either one month LIBOR or 5% plus (ii) a margin of between 5.0% and 5.5%, whilst the unused line fees on the un-drawn amount, ranges between 0.25% and 0.5% depending on the un-drawn amount.

The lenders have been issued with warrants over 5,018,414 shares (representing 2.5% of current shares in issue). The warrants have a ten year life and an exercise price of 98.052p per warrant.

On 12 January 2011 the Group completed the assignment of its debt facility with Fortress to Paladin Labs Inc. details of which are described in Note 12 Post balance sheet events. The warrants issued on 27 March 2007 were unaffected by the refinancing.

(a) Debt instrument

The debt instrument and the warrant instrument have been accounted for separately.

The fair value of the debt element for initial recognition was measured at amortised cost. The fair value of the debt at initial recognition, represented the value of the cash received less the fair value of the warrants issued. No additional warrants were issued in relation to the £17.0m drawn down during 2008, the £5.0m drawn down during 2009 or the additional £8.0m drawn down during 2010. As the debt is subsequently measured at amortised cost, the initial £20.0m is accreted to the repayment amount of £20.0m at maturity, using the effective interest rate method. The effective interest rate was 11.35% (2009: 12.09%) for the year. The amortised cost of the debt at 31 December was £44.4m (2009: £36.5m).

	2010 £m	2009 £m
At 1 January 2010		
Net funds drawn	38.6	37.0
Cumulative accretion of loan warrants	(1.1)	(1.9)
Carrying value of set up costs	(1.0)	(1.4)
	<b>36.5</b>	<b>33.7</b>
Movements during the year		
Funds drawn less funds repaid	6.8	1.6
Capitalisation of additional set up costs	(0.1)	-
Accretion of loan warrants	0.7	0.8
Amortisation of set up costs	0.5	0.4
	<b>7.9</b>	<b>2.8</b>
At 31 December 2010		
Net funds drawn	45.4	38.6
Cumulative accretion of loan warrants	(0.4)	(1.1)
Carrying value of set up costs	(0.6)	(1.0)
	<b>44.4</b>	<b>36.5</b>
Less current portion	(12.0)	(1.0)
	<b>32.4</b>	<b>35.5</b>

(b) Warrant liability

The warrant instrument is a derivative financial liability.

The warrants have been accounted for as a current liability as the warrant agreement provides a choice to the lender over how and when the contract is settled.

The fair value of the warrants issued to the lenders on 27 March 2007 of £3.0m, was determined by the use of the Binomial Tree valuation model. The fair value of the warrants as at 31 December 2010 was £2.8m (2009: £2.4m) and resulted in an increase in value of £0.4m (2009: £0.2m) being recognised in the Income Statement. The significant inputs into the model were the share price for the period leading up to the grant date being the closing market price on those dates, the closing market value at 31 December 2010, exercise price of the grant, dividend yield of 0%, expected life of the warrants, and an annual risk-free interest rate based on UK Government bond yields-to-maturity as at valuation date. The volatility measured at the standard deviation of expected share price returns is based on the ProStrakan Group share value over the expected life (for 2010) whereas in previous years this was evaluated using a broad range of comparable companies.

	2010 £m	2009 £m
At 1 January 2010	2.4	2.2
Movement in fair value charged to income statement	0.4	0.2
At 31 December 2010	<b>2.8</b>	<b>2.4</b>

## 11. Cash generated from operations

### Continuing operations

	Group		Company	
	2010 £m	2009 £m	2010 £m	2009 £m
Loss for the year	(1.0)	(15.6)	(5.1)	(3.8)
Adjustments for:				
- tax	0.4	0.6	-	-
- depreciation	0.3	0.3	-	-
- amortisation (including write-down of product rights)	4.4	4.2	-	-
- profit on sale of products rights, property, plant and equipment (see below)	-	(1.0)	-	-
- net movement in provisions for liabilities and charges	0.4	(0.2)	-	-
- charges for share-based employee benefits	0.4	(0.9)	0.3	(1.0)
- finance income	(0.1)	(0.2)	(0.2)	(0.2)
- finance cost	6.4	5.4	1.0	1.7
- movement in fair value of warrants	0.4	0.2	-	-
- changes in working capital (excluding the effects of acquisition and exchange difference on consolidation):				
- inventories	(1.2)	0.9	-	-
- trade and other receivables	(10.9)	(0.5)	(5.6)	(2.3)
- trade and other payables	1.3	(7.2)	7.8	19.9
- deferred income	(1.5)	6.8	-	-
Cash (utilised)/generated from continuing operations	(0.7)	(7.2)	(1.8)	14.3

In the cash flow statement, proceeds from sale of property, plant and equipment comprise:

Net book amount	-	0.4	-	-
Profit on sale of product rights, property, plant and equipment	-	1.0	-	-
Proceeds from sale of property, plant and equipment	-	1.4	-	-

### Non-cash transactions

The principal non-cash transactions were the issue of equity instruments to employees and Directors.

### Discontinued operations

	Group		Company	
	2010 £m	2009 £m	2010 £m	2009 £m
Loss for the year	-	(0.2)	-	(0.2)
Adjustments for:				
- net movement in provisions for liabilities and charges	-	0.2	-	0.2
- changes in working capital (excluding the effects of acquisition and exchange difference on consolidation):				
- trade and other receivables	-	-	-	-
- trade and other payables	-	(7.8)	-	(7.8)
Cash utilised by discontinued operations	-	(7.8)	-	(7.8)

## 12. Post balance sheet events

### (a) Refinancing

On 16 December 2010 the Company announced that it had entered into a strategic relationship with Paladin Labs Inc. ("Paladin"), the Canadian based international specialty pharmaceutical company, in which Paladin (through its wholly-owned subsidiary, Chimigen Inc.) would acquire, by way of assignment, ProStrakan's existing secured debt facility, with the addition of certain conversion rights, and would be granted an exclusive licence to ProStrakan's products for certain emerging territories. On the 7 January 2011 at a General Meeting of the Company, shareholders approved the assignment of the Company's existing debt facility with Fortress Investment Group, Morgan Stanley and funds managed by Och-Ziff Capital Management Group to Paladin. The assignment was completed on the 12 January 2011.

The agreement builds on the relationship which already existed between the two companies under which Paladin already had in-licensed the rights to distribute Abstral and Sancuso in Canada. The new relationship broadens this existing partnership, with Paladin being granted exclusive licence to distribute all of ProStrakan's products, including Abstral, Sancuso, Rectogesic, Xomolix and Tostran, in certain specific territories for which ProStrakan does not already have distribution agreements. These territories include: Canada, Latin America, Sub-Saharan Africa and Israel. In addition, during the term of the debt facility, Paladin have the right to license any new products acquired or licensed by ProStrakan for those same territories and on the same terms and conditions.

The £50.0m secured facility is provided by Paladin in Canadian Dollars at a rate of interest of 10.5% compared with a blended rate of 11.9% on the original facility. Paladin have the option to convert all or part of the outstanding principal debt into new ProStrakan shares at a price of £1.10 per ordinary share, but cannot convert during the initial six months of the life of the amended agreement. In the event of a change of control of ProStrakan during the initial six months (and providing Paladin requires repayment of the facility), Paladin are entitled to receive a payment equivalent to the balance of interest for the first year of the loan, together with an early repayment fee of £2.0m (CAD\$3.3m). Full details of the facility were set out in the circular sent to shareholders on 21 December 2010.

After fees and an early repayment interest payment paid to the original lenders, the Group received a further £2.4m in cash from the facility. Following the assignment and subsequent additional draw down, the amount outstanding to Paladin Labs Inc is CAD\$77.2m (£50.0m) with the assignment occurring at an exchange rate of 1.54465 CAD\$ = £1. The carrying value of the debt instrument will be re-valued at period ends and as such creates a foreign exchange exposure risk for the Group. The Group has reviewed the various options available to it in order to hedging part of all of the borrowings and have determined that due to the cost of such instruments not to put in place foreign exchange hedging measures.

The facility can be repaid at any time with Paladin's consent. It is also repayable on demand by Paladin on the occurrence of certain events of default and upon the Company being subject to a change of control. On 17 February 2011 the Company and KHK (as defined below) received a consent letter from Paladin consenting to the early repayment of the whole of the facility conditional upon completion of the proposed takeover of the Company by KHK as further described in section (b) below, which will result in the payments described above being made. Following repayment, Paladin's rights to license any new products acquired or licensed by ProStrakan for those same territories expires.

Paladin will be entitled, for so long as either any sums remain outstanding under the facility or Paladin holds at least 15% of the issued share capital of the Company, to appoint one non-executive director to the Board of ProStrakan. On 12 January 2011, Jonathan Goodman, Paladin's CEO, joined the Board of ProStrakan as a Non-executive Director.

### (b) Recommended cash acquisition of ProStrakan Group plc

On 21 February 2011, the boards of Kyowa Hakko Kirin Co., Ltd. ("KHK") and ProStrakan Group plc ("ProStrakan") announced that they had reached agreement on the terms of the recommended cash acquisition by KHK of the entire issued and to be issued share capital of ProStrakan (the "Acquisition"). Under the terms of the Acquisition, ProStrakan Shareholders will be entitled to receive 130 pence in cash for each ProStrakan Share, valuing the entire issued and to be issued ordinary share capital of ProStrakan at approximately £292 million (¥39,420 million). The price of 130 pence per ProStrakan Share represents a premium of approximately 41 per cent to the closing price of 92.5 pence per ProStrakan Share on 12 November 2010, being the last business day immediately prior to the start of ProStrakan's current offer period; and 100 per cent to 64.9 pence, being the volume weighted average closing price per ProStrakan Share over the 6 months prior to 12 November 2010, being the last business day immediately prior to the start of ProStrakan's current offer period.

The Acquisition would represent a new opportunity for ProStrakan's continued development and could, through the complementary nature of ProStrakan and KHK, in terms of products, geography and infrastructure, allow ProStrakan to grow at a faster pace and to offer to patients and clinicians across Europe and the US, in time, a broader range of medicines.

In consideration for KHK making the Acquisition, ProStrakan has agreed to pay to KHK an inducement fee equal to one percent of the value of the Acquisition if, prior to the date upon which the Acquisition lapses or is withdrawn various events occur. In addition, ProStrakan has made various non-solicitation undertakings and has offered KHK the right, under certain circumstances to match a superior proposal if one should be received. Details of the Implementation Agreement agreed between the parties can be found in the Scheme Document sent to shareholders on 8 March 2011.

It is proposed that the Acquisition be implemented by means of a Scheme of Arrangement under Part 26 of the Companies Act 2006. Full details of the Acquisition are set out in the Scheme Document sent to shareholders on 8 March 2011.

## 13. Principal Risks and Uncertainties

The Group is exposed to a number of risks in the operation of its business, the most important of which are discussed below.

### Marketed products

In the year ended 31 December 2010, the Group's product sales accounted for 89% (£89.2m) of total revenue versus 2009 at 94% and (£74.4m) respectively. Of the currently marketed products, the largest in-market sales were generated by Adcal-D3, Sancuso, Isotard XL, Tebetane, Pencial, Rectogesic, Abstral and Droperidol (Xomolix). There can be no assurance that this level of product sales from marketed products can be either maintained or increased in the future. Product sales may be affected by adverse market developments, including the market for a particular product not developing in the manner predicted by the Group, downward pressure on pricing from governments and other third parties to limit healthcare costs, increased competition and the withdrawal of a product for regulatory reasons or otherwise.

### Commercial success in the US

The Group has a strong track record of growth in Europe and commenced its commercial operations in the US during late 2007 ahead of the launch of its first US product, Sancuso. The Group has recently received approval to launch Abstral in the US. The commercial success of these two products in the US will be a key factor in the level of future success of the Group. There can be no assurance that the Group will be successful in the US.

### Manufacturing

ProStrakan outsources all of its manufacturing operations to third party suppliers. The Group cannot guarantee its ability to secure continuity of product supply from these third party suppliers. During 2010, the business experienced a major product interruption in the supply of one of its key products which led to a material financial impact. The business is currently managing the transfer of several existing products to new suppliers which by its nature creates a risk to continuity of product supply.

### Competition and intellectual property risk

The Group's business depends both on the continued successful commercialisation of existing pharmaceutical products and the in-licensing, product acquisition and/or development, obtaining and maintaining marketing authorisations and subsequent successful commercialisation of new pharmaceutical products. The risks faced by the Group in relation to each of its products and product candidates differ substantially depending on whether they are in the market, seeking marketing authorisation(s) or in clinical development. Due to the inherent risk in the development of pharmaceutical products, it is probable that not all of the product candidates in the Group's portfolio will successfully complete development, obtain market authorisations, achieve satisfactory price reimbursement and be launched. Further, the Group's products may have to be removed from the market for regulatory reasons after approval has been given.

### Products seeking marketing authorisations

The Group is currently seeking a marketing authorisation for Sancuso in Europe and for Rectogesic in the US during 2011. There can be no assurance that any product for which a marketing authorisation is sought will receive such authorisation and price reimbursement (if applicable) in those territories for which market authorisations are sought or if they do, that they will be successfully commercialised in those territories.

### Clinical and regulatory risk

Insufficient efficacy in the chosen indication or unacceptable side-effect profiles may cause a product candidate to fail in clinical development or limit its applicability should it reach a commercial stage. Lack of performance by third party clinical research organisations or an inability to recruit patients may cause undue delays in clinical trials. Clinical and regulatory issues may arise or changes to the regulatory environment may occur that lead to delays, further costs, reduction in the commercial potential of a product candidate or the cessation of programmes. Ethical, regulatory or marketing approvals may be delayed or withheld or, if awarded, may carry unacceptable conditions to further development or commercial success. As both the product and its manufacturer are subject to continual review there can be no assurance that such marketing authorisation, once granted, will not be withdrawn or restricted. If there are changes to the application of legislation or regulatory policies, or problems are discovered with the product or the manufacturer, or if the Group fails to comply with regulatory requirements, the regulators could take action which may negatively impact the Group's ability to sell the products or the Group may incur substantial additional expense to comply with the regulatory requirements. In addition, in certain territories, even after obtaining a marketing authorisation, the Group may decide to seek price reimbursement approval (if applicable), which may delay the marketing of the Group's products, limit their commercial potential or mean that the product cannot be commercialised at all.

### Commercialised product risk and development risk

The Group's ability to compete effectively with other companies will depend in part on its ability to obtain and maintain patent and/or trademark protection for certain of its products and product candidates, preserve its trade secrets, defend and enforce its rights against infringement and operate without infringing the proprietary or intellectual property rights of third parties. The validity and enforceability of patents and/or trademarks may involve complex legal and factual issues resulting in a high degree of uncertainty as to the extent of the protection provided.

### Economic risk

The successful development and commercialisation of pharmaceutical products carry a high level of risk and the returns may be insufficient to cover the costs incurred. Restrictions on health budgets worldwide or on the prices that may be charged for new medicines through competitive or other pressures may limit a medicine's sales potential. The Group may not be able to adequately fund its own development or commercialisation activities to compete with larger, more established competitors and it may fail to attract partners on favourable terms or recruit the appropriate calibre of staff to help develop or commercialise its products. Furthermore, selected partners may fail to perform or commit the resources necessary to develop or commercialise the Group's products successfully.

## Financial risk

The Group is currently loss making and sustainability is dependent upon generating cash flows from successful development and commercialisation of the Group's products. Until then, the Group will be dependent upon additional funding through completion of licensing deals or through injection of capital from debt or equity sources. There can be no assurances that such funding will be achieved on favourable terms, if at all. Failure to generate additional funding may lead to postponement or cancellation of programmes and/or a scale-back of operations.

Since the refinancing completed in January 2011 the Group has a Canadian dollar debt facility for approximately £50.0m upon which it currently pays interest at a rate of 10.5% on a quarterly basis and which will require capital repayment in January 2014 unless the lender elects to convert part or all of the outstanding capital sum into equity of the Group. The facility contains a number of covenants. If the Group is unable to meet these covenants at any point then the capital sum will become fully repayable.

The Group is exposed to a number of foreign exchange risks. The principal foreign exchange risk is associated with the debt facility described above which is denominated in Canadian dollars. Movements in the exchange rate between the Canadian dollar and Sterling will have an impact on both the pounds sterling cost of interest payments due and on the pounds sterling cost of repaying the outstanding capital sum when it falls due. The Group has only minor sources of income in Canadian dollars which it receives from its distribution partners. The Group has not entered into any hedging instruments for either the interest or capital elements of the facility due to the high cost of these instruments and as a result has a non-hedged foreign exchange exposure.

## 14. Responsibility Statement

The Annual Report for the year ended 31 December 2010 complies with the Disclosure and Transparency Rules of the United Kingdom's Financial Services Authority in respect of the requirement to produce an Annual Financial Report. Andrew McLean, Company Secretary, confirmed on behalf of the Board that, to the best of each person's knowledge and belief:

- the financial statements, prepared in accordance with IFRSs as adopted by the EU, give a true and fair view of the assets, liabilities, financial position and loss of the Group and Company; and
- the Directors' report contained in the Annual Report includes a fair review of the development and performance of the business and the position of the company and Group, together with a description of the principal risks and uncertainties that they face.